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Mid-urethral slings for treatment of stress urinary incontinence – long- and mid-term follow-up

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Academic dissertation

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LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following original publications, referred to in the text by their Roman numerals:

I Nilsson CG, Palva K, Rezapour M, Falconer C. Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Aug;19(8):1043-7.

II Palva K, Nilsson CG. Effectiveness of the TVT procedure as a repeat mid-urethra operation for treatment of stress incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 2009 Jul;20(7):769-74.

III Palva K, Rinne K, Aukee P, Kivela A, Laurikainen E, Takala T, Valpas A, Nilsson CG. A randomized trial comparing tension-free vaginal tape with tension-free vaginal tape-obturator: 36-month results. Int Urogynecol J Pelvic Floor Dysfunct. 2010 Sep;21(9):1049-55.

IV Palva K, Nilsson CG. Prevalence of urinary urgency symptoms decreases by mid-urethra sling procedures for treatment of stress incontinence. Int Urogynecol J Pelvic Floor Dysfunct. Int Urogynecol J Pelvic Floor Dysfunct. 2011 Aug 18 [Epub ahead of print] DOI:10.1007/s00192-011-1511-3.

Publication III has appeared also in the academic dissertation of Kirsi Rinne (Kuopio 2010).

ABBREVIATIONS

BMI	Body mass index (kg/m²)
DI	Detrusor instability
DIS	Detrusor Instability Score
DO	Detrusor overactivity
EQ-5D	EuroQuality of life – five dimensions
GSI	Genuine stress incontinence
ICS	the International Continence Society
IIQ	Incontinence Impact Questionnaire
IUGA	the International Urogynecological Association
IVS	Intravaginal slingplasty
LOCF	Last-observed result carried forward
LUTS	Lower urinary tract symptoms
MMK	Marshall-Marchetti-Krantz
MUI	Mixed urinary incontinence
OAB	Overactive bladder
PFMT	Pelvic floor muscle training
PGI	Patient's Global Impression
PVR	Post-void residual (urine)
RCT	Randomized controlled trial
SPARC	Supra Pubic Arc – sling
SUI	Stress urinary incontinence
TOT	Transobturator Tape
TVT	Tension-free Vaginal Tape
TVT-O	Tension-free Vaginal Tape – Obturator
UCM	Urethrocystometry
UCP	Urethral closure pressure
UDI	Urogenital Distress Inventory
UISS	Urinary Incontinence Severity Score
UTI	Urinary tract infection
UUI	Urgency urinary incontinence
VAS	Visual Analogue Scale

ABSTRACT

Urinary incontinence is a common problem, affecting one third of the women at least at some time during their lives. The prevalence of urinary incontinence increases with advancing age, and the everyday impact of incontinence on women and on health services is enormous. Urinary incontinence is usually divided into three different subtypes, of which stress urinary incontinence (SUI) is the most common. Surgical treatment is often needed to cure SUI, and modern mid-urethra sling procedures give the possibility to cure this condition with a low risk of adverse events, a problem often associated with the so-called traditional incontinence operations. Life expectancy among women in Western countries has grown beyond 80 years of age. Long-term efficacy of treatment options for urinary incontinence therefore becomes an important issue in a world with limited economic resources.

The purpose of the present study was to prospectively evaluate the long-term efficacy and safety of the first minimally invasive mid-urethral tape procedure, the Tension-free Vaginal Tape (TVT) procedure. The long-term (5-year) follow-up results of the TVT procedure as a repeat operation after an unsuccessful mid-urethral tape operation were studied and the reasons for failure of the first operation were analyzed. Another purpose was to compare the original TVT procedure with a newer modification, the Tension-free Vaginal Tape – Obturator (TVT-O) procedure within a multi-centre, randomized context in order to find out possible differences between these procedures regarding efficacy and complications and the effects on symptoms of urgency.

The first study of the present thesis is a prospective, Nordic, three-centre follow-up study of 90 women suffering from SUI, who were treated by means of the TVT procedure. The mean follow-up time was more than eleven years, and the study is the first to be published in connection with more than ten years of follow-up. The second study is a retrospective analysis of 20 women who were treated with a repeat TVT procedure after an unsuccessful primary mid-urethral tape procedure. The third and fourth studies concern 273 women in seven centres in Finland who were randomly assigned to the TVT and TVT-O procedures, the 3-year follow-up results of which are presented in this thesis.

After eleven years of follow-up, 90% of the women had a negative cough stress test result and a negative 24-h pad test result. The subjective cure rate measured as the women's global impression of cure was 77%, the rate of improvement 20%, and only 3% thought that the treatment had failed. No late-onset adverse effects were found. The repeat TVT procedure was successful in 75% of the cases when women who were cured and women who were significantly improved were included. The reasons for failure of the first operation could be separated into four different groups: tape material-related, operation technique-related, concomitant illness-related and a group with no identifiable reason. There were no intra-operative complications during the repeat operation.

In the randomized trial comparing the TVT with the TVT-O procedure a cough stress test results were negative in 94.6% and 89.5% of the women in the two groups, respectively, after a 3-year follow-up period. There were no statistical differences in the cure rate or the rate of complications between the two procedures. Symptoms of urgency were analyzed more closely and the main finding was that the prevalence of urgency symptoms decreased significantly after both mid-urethral sling procedures.

The TVT operation was found to be an effective and safe procedure even after eleven years of follow-up. Long-term follow-up after a repeat TVT procedure revealed that the TVT procedure can well be considered after an unsuccessful mid-urethra tape procedure, because 75% of the patients showed significantly improvement of their incontinence. The TVT and TVT-O procedures showed no statistically significant differences in efficacy and rate of complications after three years of follow-up. In most cases these procedures alleviate preoperative symptoms of urgency and the risk of developing *de novo* urgency is low.

YHTEENVETO

Virtsankarkailu on yleinen ongelma, joka koskettaa noin kolmasosaa naisista ainakin joskus elämän aikana. Virtsankarkailun esiintyvyys kasvaa iän lisääntyessä ja virtsankarkailun vaikutus naisten jokapäiväiseen elämään ja yhteiskuntaan on suuri. Virtsankarkailu jaetaan yleisesti kolmeen eri päätyyppiin, joista ponnistusvirtsankarkailu on yleisin. Leikkaushoitoa tarvitaan usein ponnistusvirtsankarkailun parantamiseksi. Nykyaikaiset keskiuretraa tukevat nauhaleikkaukset antavat mahdollisuuden hoitaa ponnistusvirtsankarkailua niin, että haittavaikutusriski on pieni, toisin kuin perinteisillä virtsankarkailuleikkauksilla. Hoitovaihtoehtojen pitkäaikaistulokset ovat tulleet yhä merkittävämmiksi myös rajallisten taloudellisten resurssien takia, koska länsimaissa naisilla eliniän odote on kasvanut jo yli 80 ikävuoteen.

Tämän väitöskirjatyön tarkoituksena oli prospektiivisesti tutkia ensimmäisen kehitetyn keskiuretraa tukevan nauhaleikkauksen eli TVT:n tehokkuutta ja turvallisuutta pitkän ajan seurannassa. Tarkoituksena oli myös arvioida TVT:n vaikuttavuutta uudelleenleikkauksena pitkän ajan (5 v) seurannassa aiemman epäonnistuneen keskiuretranauhaleikkauksen jälkeen ja analysoida syitä ensimmäisen leikkauksen epäonnistumiseen. Lisäksi TVT -leikkausta verrattiin satunnaistetussa monikeskustutkimuksessa yhteen uudempaan TVT -leikkauksen muunnelmaan, TVT-O -leikkaukseen. Tarkoituksena oli selvittää, onko leikkausten välillä eroja tehokkuudessa, haittavaikutuksissa ja pakkovirtsankarkailuoireiden kehittymisessä pidemmän ajan seurannassa.

Tutkimuksen ensimmäinen osatyö on pohjoismainen kolmikeskustutkimus, jossa 90 ponnistusvirtsankarkailusta kärsivää naista leikattiin TVT -leikkauksella. Keskimääräinen seuranta-aika ensimmäisessä tutkimuksessa oli 11½ vuotta ja se on ollut ensimmäinen yli 10 vuoden seurannan jälkeen julkaistu tutkimus TVT -leikkauksesta. Toisessa osatyössä tutkittiin retrospektiivisesti 20 naista, joille oli tehty TVT uusintaleikkauksena aiemman epäonnistuneen keskiuretranauhaleikkauksen jälkeen. Tutkimuksen kolmannessa ja neljännessä osatyössä tutkimuspopulaation muodostavat 273 naista, jotka seitsemässä suomalaisessa keskuksessa satunnaistettiin joko TVT- tai

TVT-O -leikkaukseen ja kolmen vuoden seurantatulokset tutkimuksesta on esitetty tässä väitöskirjassa.

Yhdentoista vuoden seurannan jälkeen 90% naisista oli sekä yskäisykokeen että 24 tunnin vaippatestin mukaan parantuneita. Oman arvionsa mukaan naisista 77% koki itsensä täysin parantuneeksi, 20%:lla tilanne oli selvästi parempi kuin ennen leikkausta ja vain 3% ajatteli, että leikkaus oli epäonnistunut. Pitkän ajan seurannassa mahdollisesti ilmaantuvia haittavaikutuksia ei todettu. Uudelleenleikkauksena TVT -leikkauksesta oli selvästi apua 75%:lle tutkituista, kun sekä objektiivisesti täysin parantuneet että selvästi apua saaneet laskettiin yhteen. Syyt ensimmäisen leikkauksen epäonnistumiseen jaoteltiin neljään eri ryhmään: nauhamateriaaliin liittyviin, operaatiotekniikkaan liittyviin, potilaan muihin sairauksiin liittyviin syihin sekä ryhmään, jossa selvästi havaittavissa olevaa syytä ei löytynyt. Uudelleenleikkauksen yhteydessä ei tullut komplikaatioita.

Satunnaistetussa TVT- ja TVT-O -leikkauksia vertailevassa tutkimuksessa kolmen vuoden seurannan jälkeen yskäisykoe oli negatiivinen 94.6% naisista TVT ryhmässä ja 89.5% naisista TVT-O ryhmässä. Leikkauksien välillä ei ollut tilastollisesti merkitseviä eroja tehokkuudessa tai haittavaikutuksissa kolmen vuoden seurannassa. Pakkovirtsankarkailuoireita analysoitiin lähemmin ja havaittiin, että pakko-virtsankarkailuoireet vähenivät merkittävästi kummankin keskiuretranauhaleikkauksen jälkeen.

Johtopäätöksinä tutkimuksesta voidaan todeta, että TVT-leikkaus osoittautui tehokkaaksi ja turvalliseksi ponnistusvirtsankarkailun hoitomuodoksi myös pitkän, yli 11 vuoden seurannan jälkeen. TVT -leikkausta voidaan käyttää myös uudelleenleikkauksena aiemman epäonnistuneen keskiuretranauhaleikkauksen jälkeen, koska 75% potilaista saa siitä selvästi apua uusiutuneeseen vaivaansa. TVT- ja TVT-O -leikkauksilla ei ole tilastollisesti merkitseviä eroja tehokkuudessa eikä komplikaatioissa kolmen vuoden seurannan jälkeen. Molemmat näistä keskiuretranauhaleikkauksista yleensä vähentävät ennen leikkausta esiintyneitä tihentynyttä virtsaamistarvetta ja pakko-virtsankarkailuoireita ja uusien pakkovirtsankarkailuoireiden ilmaantuminen on vähäistä.

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INTRODUCTION

Urinary incontinence is a major health problem and has significant effects on women's daily lives. Incontinence affects women's social lives, work, travel and hobbies, and causes hygiene problems and embarrassment [Imamura *et al.* 2010]. The economic impact on society is enormous, as approximately 35% of women reported incontinence in the preceding 30 days in an European epidemiological study [Hunskaar *et al.* 2004]. The most prevalent type of incontinence is stress urinary incontinence (SUI) in women under 55 years of age. At later ages mixed urinary incontinence becomes the most common type of incontinence [Hunskaar *et al.* 2004]. Conservative treatment options are the first-line management choices for SUI, but they are effective only in some of the women. Surgical treatment has the possibility to cure SUI, and objective long-term results have been reasonable for traditional incontinence operations, but they carry a high risk of complications. Long-term follow-up has revealed decreasing subjective cure rates [Kjølhede 2005]. Long-term evaluation is important, because life expectancy of women in Western countries is currently over 80 years and the mean age at which incontinence operations are performed is around 50 years [Kjølhede 2005]. Not until the development of the modern mid-urethral sling procedures has incontinence surgery met the expectations of minimal invasiveness and low risks of complications. The present study was carried out to evaluate the long-term efficacy of a primary mid-urethral tape procedure, the Tension-free Vaginal Tape (TVT) operation and we also evaluated the performance of the TVT procedure as a repeat operation. The efficacy and complications of the TVT procedure and its newer modification, the Tension-free Vaginal Tape−Obturator (TVT-O) operation, are evaluated in a randomized context.

REVIEW OF THE LITERATURE

Definitions and classification of urinary incontinence

The new joint report of the International Urogynecological Association (IUGA) and the International Continence Society (ICS) on the terminology of female pelvic floor dysfunction from year 2010 states: urinary incontinence is a complaint of involuntary loss of urine and it is further divided into eight different definitions. The most common types of these are stress urinary incontinence (complaint of involuntary loss of urine on effort or physical exertion, or on sneezing or coughing), urgency urinary incontinence (complaint of involuntary loss of urine associated with urgency) and mixed urinary incontinence (complaint of involuntary loss of urine associated with urgency and also with effort or physical exertion or on sneezing or coughing). In addition to the three above-mentioned, there are postural incontinence, nocturnal enuresis, continuous incontinence, insensible incontinence and coital incontinence [Haylen *et al.* 2010].

Theories of continence mechanisms

The history of surgical treatment of SUI includes a description of over 200 different procedures, a fact that reveals our limited knowledge of the underlying causes of the condition. The cause of SUI is multi-factorial and complex and still not completely resolved [DeLancey 1994]. The first theories on continence mechanisms were based on radiological studies and it was thought that the urethra has two sphincters, a voluntary external sphincter and an involuntary internal sphincter, the latter of which alone is able to close the urethra [Emmet *et al.* 1948, Ingelman-Sundberg 1952]. Striated muscle fibres form the external sphincter: they are circular in the upper part of the urethra and concentrated further down at the posterior wall of the urethra, adjacent to the vagina [Enhörning 1961].

The pelvic floor consists of the levator ani muscular plate, in which three separate parts are identified: the pubococcygeus, iliococcygeus and puborectalis muscles. The paired pubococcygeus muscles have a triangular opening in the mid-line and this part is closed by the urogenital diaphragm. The urethra penetrates this membranous diaphragm and part of the urethra is situated above the diaphragm/pelvic floor (the intra-pelvic portion of the urethra). Enhörning commenced to measure pressures simultaneously in the bladder and in the urethra during coughing in healthy and in stress-incontinent women. He found that the resting urethral pressure exceeded the simultaneously recorded intra-vesical pressure. During coughing the intra-vesical and the intra-urethral pressure increased in healthy continent woman. This phenomenon was thought to explain the mechanism of continence and was called the pressure-transmission theory. According to this theory the proximal portion of the urethra is normally intra-pelvic and loosely attached to tissues in the pelvic floor and the proximal part of the urethra was thus thought to be of greatest importance as regards continence. If the supporting tissues are weakened, the normal transmission of intra-abdominal pressure to the urethra disappears and leakage occurs. This theory led to the development of surgical procedures which correct the position of the bladder neck and the proximal part of the urethra [Enhörning 1961].

In one study it was shown that urethral pressure increases 240 milliseconds earlier than the intra-abdominal pressure during stress and that pressure rise in the urethra frequently exceeds the increase in intra-abdominal pressure [Constantinou and Govan 1982]. This finding indicates that striated muscle contraction is involved in the continence mechanism in addition to the passive compression of the urethra against supportive tissues [DeLancey 1994]. It has also been shown that the greatest increase in urethral pressure occurres at the distal part of the urethra rather than at the proximal part [Constantinou and Govan 1982].

Research activity in the field of urinary incontinence and urethral physiology was intense during the 1970's in the Nordic countries. Simultaneous urethro-cystometry using a microtransducer technique instead of fluid- or gas-filled catheters was developed [Asmussen and Ulmsten 1976]. Research was also directed towards investigations on innervation of the urethra. Studies on the urethra of the female guinea-pig showed that the density of adrenergic nerve terminals increased when moving from the proximal part of the urethra towards more distal parts [Ulmsten *et al.* 1977]. In the human urethra the

density of adrenergic nerve terminals was found to be evenly distributed throughout the length of the urethra [Ek 1978]. The finding of a high pressure zone and a peak pressure at the mid-urethra in women undergoing investigation by means of simultaneous urethro-cystometry was reported in 1982 by Ulmsten [1982]. Another study confirmed the finding by means of voiding urethro-cystography, which demonstrated that in continent women the maximal urethral pressure peak corresponded with the mid-point of the functional urethra (at 53% of the total functional length distal to the internal urethral meatus) [Westby *et al.* 1982]. These findings and those reported by Zacharin in 1968, which showed that anterior and posterior pubo-urethral ligaments and a connecting ligament comprise a suspensory system of the urethra, which is attached to the distal two-thirds of the urethra [Zacharin 1968], made it evident that mechanisms other than pressure transmission to the intra-pelvic part of the urethra and the bladder neck are involved in female urinary continence.

In 1990 Petros and Ulmsten launched the "integral theory", according to which stress and urgency urinary symptoms may both be derived, for different reasons, from the same anatomical defect, "a lax vagina", which is caused by weakening of supportive connective tissue structures of the urethra and the vagina, allowing stress urinary incontinence. It has also been shown, that there are differences in connective tissue structure and concentration between continent and incontinent women [Ulmsten *et al.*1987, Falconer *et al.* 1994]. According to the integral theory, the same weakening of tissues also leads to activation of hypothesized stretch receptors of the bladder base and symptoms of urgency [Petros and Ulmsten 1990]. This latter part of the theory has been controversial since its introduction and the presence of stretch receptors has never been confirmed [Petros and Woodman 2008]. The theory was therefore later called the "Mid-urethra theory", in which focus has been on the role of the pubo-urethral ligaments and vaginal support of the mid-urethra from beneath.

In 1994 similar ideas were presented by DeLancey, according to whom the urethra is compressed against a hammock-like supportive layer on straining or coughing and continence is thus maintained. Support of the urethra varies along its length. At the level of the bladder neck the vagina attaches laterally to the arcus tendineus of the endopelvic fascia. Closer to the meatus externus of the urethra the endopelvic fascia increases in quantity and density. The medial portion of the levator ani muscle, the pubococcygeus

muscle, is also connected to the arcus tendineus through the endopelvic fascia. The endopelvic fascia spreads out as a hammock beneath the urethra. The urethro-vaginal sphincter muscles lie at the distal part of the urethra. These are important findings indicating that not only the proximal part of the urethra but also the more distal parts of the urethra are involved in the continence mechanism [DeLancey 1994].

Prevalence of urinary incontinence

Reported prevalence rates of urinary incontinence vary across studies because of differences in definitions, questionnaires used, study populations and survey methods [Irwin *et al.* 2006]. The overall prevalence of urinary incontinence in women over 18 years of age was 13.1% in a large population-based epidemiological study in five countries (Canada, Germany, Italy, Sweden, and the United Kingdom) and SUI was the most common type (48.9%) [Irwin *et al.* 2006]. Prevalence increased with age so that in women of ≤39 years of age the prevalence of any kind of urinary incontinence was 7.3%, in women of 40−59 years of age 13.7% and in women of ≥60 years of age, 19.3 % [Irwin *et al.* 2006].

In the Norwegian study the prevalence of incontinence was 12% for women of <30 years of age and the highest prevalence, 40%, was observed in the group of women of more than 90 years of age. There was a peak of prevalence of 30% in the group of 50- to 54-year-old women. In this study the incontinence symptoms were classified as stress, urge or mixed and half of the women were experiencing symptoms of SUI alone [Hannestad *et al*. 2000].

More than five thousand 25 to 55 year old women in Finland completed a questionnaire concerning urinary incontinence symptoms, when participating in a cervical cancer screening program. The overall prevalence of urinary incontinence in this age group was 20.1% and stress incontinence was the most common type (73%) [Mäkinen *et al.* 1992].

The prevalence of different types of urinary incontinence in a Finnish population aged 70 and older was studied in 1999. The study reported a prevalence of 23% for stress urinary incontinence, 6% for urgency urinary incontinence and 30% for mixed urinary incontinence, respectively [Nuotio *et al.* 2003].

Other epidemiological studies have shown a similar increase in the prevalence of urinary incontinence with age [Milsom 2000, Hunskaar *et al.* 2004]. Stress urinary incontinence is the most common type of incontinence in women under 55 years of age and at a later age mixed urinary incontinence becomes most common [Hunskaar *et al.* 2004]. The mean annual incidence rate of urinary incontinence has been found to be 3% [Samuelsson *et al.* 2000].

Effect of time on lower urinary tract symptoms in women

In a population-based study lower urinary tract symptoms were evaluated in five countries and over 12,000 women (age ≥18 years) answered the questionnaire. All lower urinary tract symptoms increased in prevalence with advancing age and the prevalence of any lower urinary tract symptoms was 67%. These symptoms included urgency, nocturia, urgency urinary incontinence, mixed urinary incontinence, other incontinence, intermittency, slow stream, postmicturition dribble and stress urinary incontinence. Some form of urinary incontinence was reported by 13% of the women and half of this was SUI [Irwin *et al*. 2006].

The natural history of a condition is its epidemiological development without intervention. This is very difficult to study, because in population-based studies all women are usually included, not only those who have not been treated. In a prospective study a 22% incidence of incontinence during a year was found among women over 60 years of age. In the same study the one-year remission rate of incontinence was 11% for women over 60 years of age [Herzog *et al.* 1990].

In a prospective study using random sampling a cohort of 2109 women was followed for approximately five years after first evaluation. New onset of incontinence were reported by 8% of the women, incontinence progressed in 12%, decreased in 9% and became resolved in 9% of the women. It is not clear whether the level of remission reflects active treatment or intervention or whether it is part of the natural course of incontinence [Thom *et al*. 2010].

Impact of incontinence on women and society

Urinary incontinence is a major health problem and has significant effects on women's quality of life. Daily living, hygiene, emotional and psychological health and lifestyle are changed because of incontinence [Imamura *et al.* 2010]. Feelings of low self-esteem, embarrassment and helplessness are common among young and middle-aged women with incontinence [Ashworth and Hagan 1993]. Incontinence may have an effect on inter-personal relationships, decrease sexual function and increase institutionalization and even mortality in the aged population [Farage *et al.* 2008]. The economic impact on society is substantial. In the USA the costs for urinary incontinence have been estimated to exceed 20 billion dollars per year and most of the costs are derived from routine care, use of protection such as pads and diapers and from laundry. The estimated costs of incontinence vary between studies from 50 dollars to 1000 dollars per person per year and costs increase with severity of incontinence [Subak *et al.* 2008].

Treatment of stress urinary incontinence

Treatment options for SUI are non-surgical and surgical. Non-surgical or conservative treatment options are associated with a lower risk of adverse events than are those of surgical treatments, and are therefore recommended as first-line management. Physical treatment by way of pelvic floor muscle training (PFMT) as such, or PFMT combined with use of vaginal cones, biofeedback or electrical stimulation are possible treatment alternatives as is weight loss in overweight individuals. Most of these alternatives require special facilities and all of them demand long-term counselling and motivation of the woman to have an effect [Imamura *et al.* 2010]. Non-surgical treatments are effective in only some of the women suffering from SUI, and they seldom result in a final cure of the condition [Labrie *et al.* 2009]. Surgical treatment provides the possibility to cure SUI by means of a single intervention. The stress component of mixed urinary incontinence, including both urgency urinary incontinence and stress urinary incontinence, is often corrected by a surgical procedure and reports suggest that even the urgency symptoms might be resolved by surgery [Amundsen *et al.* 2000, Langer *et al* 2001, Choe *et al.*

2008]. This has raised questions about the effect of surgical treatment on urgency urinary incontinence symptoms.

Significance of the time of follow-up of incontinence operations

Definitions of follow-up times

In follow-up studies of incontinence surgery 3−5 years of follow-up is usually considered as long-term. This time period is probably too short to justify a definition of long-term, as the results of many operations begin to decline after 3−5 years. No generally accepted definition has been proposed by the ICS or the IUGA as to what is long-term follow-up in urogynaecological terms [Kjølhede 2005]. In a recently published Cochrane review of randomized studies of open retropubic colposuspension, three separate follow-up times were considered: ≤ one year, after the first year but before five years and ≥5 years after the operation [Lapitan *et al*. 2009]. Long-term follow-up studies are laborious, time-consuming and expensive. Women may not be willing to adhere to the study for a very long time period or they may become lost to follow-up because of migration. New illnesses and deaths make follow-up impossible. Long-term follow-up also demands a leader who is dedicated to the study and the whole subject around the study.

Short-term follow-up: ≤1 year

Use of short-term follow-up is the most common study protocol when a professional is developing a new procedure where swift results are a prerequisite for the ongoing and developing work. Short-term results under these circumstances reflect the enthusiasm of the procedure-developing professional, the accuracy of the surgical treatment and careful patient care immediately postoperatively. Short-term results have special value when the rates of failure or complications of surgery are unacceptably high [Nygaard 2006]. Many medical companies are currently developing and marketing different variations of minimally invasive slings for clinical use. Wide use of these products without good-quality evidence of their efficacy and safety is dangerous. Such newly developed products/procedures should only be used in a research context. At the moment, published

literature indicates that cure rates associated with some of the modified minimally invasive slings are inferior to those associated with traditional retropubic TVT or the original transobturator slings and some of these have even been withdrawn from the market because of complications associated with them. Examples of products withdrawn because of high complication rates are the Protegen Sling® (Boston Scientific, Natick, MA, USA), Uratape®/Obtape® (Mentor, Santa Barbara, CA, USA), Intravaginal Slingplasty® (Tyco, Mansfield, MA, USA) and the InFast® sling with InteMesh® (American Medical Systems, Minnetonka, MN, USA) [Dwyer 2011]. In one published report on the Mentor ObTape, 13.4% of the 67 treated women had vaginal extrusions of the sling. Extrusion presented at an average of 168 days (range 32 to 280) after surgery [Yamada *et al*. 2006]. In another study the extrusion rate associated with the suburethral sling procedure with the Tyco IVS sling was as high as 17% and the mean time to presentation of symptoms was 9 months (range 2 to 15 months) [Siegel *et al.* 2005].

Medium-term follow-up: 1–5 years

Despite good short-term follow-up efficacy, medium-term follow-up might reveal decreasing cure rates, which are findings important to register in order to decide on clinical practices and resource allocation. An example of this concerns the TVT-Secur, a single-incision mini-sling, the efficacy of which was good during short-term follow-up. However, at the last follow-up 30 months postoperatively only 40% of the patients were cured and many of them had undergone reoperation with a TVT procedure or a transobturator sling [Cornu *et al.* 2010].

Long-term follow-up: ≥5 years

The mean age at which incontinence surgery is usually performed is around fifty years of age [Kjølhede 2005]. The primary incontinence operation has the best prognosis. Repeat incontinence surgery is less successful than primary surgery and is associated with higher risks of complications [Awad *et al.* 1988]. Long-term follow-up studies are therefore important, because the life expectancy of women in Western countries has grown to over 80 years [Pinkhasov *et al*. 2010]. The results of long-term studies are sometimes difficult to interpret in terms of success of a surgical procedure as many medical conditions

unrelated to the incontinence operation might have an effect on the continence status of an individual. Prospective long-term follow-up is nonetheless important for registering how medical conditions affect the performance of a certain surgical incontinence procedure, thereby guiding clinicians to choose the most appropriate procedure for an individual.

Reporting of outcome measures

Evaluation of the outcome of surgical interventions is based on assessment before and after treatment. Early reports on the results of surgical treatment were mostly case reports and later there were series of cases. Evaluation of the outcome was based on the surgeon's personal assessment of the treatment without using any specific standardized tests. The reliability of such assessment is questionable. In the era of "evidence-based medicine", reporting of results of surgical treatments has undergone a revolution and this has generated a need for generally accepted standards of outcome measures. The accuracy and reproducibility of tests used for outcome interpretation are very important when different treatments are compared. Accuracy is verified if the test gives the same result as the reference standard test which defines the true disease status. Reproducibility is determined by comparing results of repeated examinations on the same object. The outcome of surgical procedures has become more and more important not only from the patient's point of view, but also because we are dealing with limited economic resources. The main goal is cure, but as important are the possible side-effects and complications of surgery. Focus is increasingly shifting to the role of patient expectations and quality of life in determining the success of surgical treatment. Recent efforts by professional associations have been directed at providing standardized outcome measures to be used in clinical and research activities. Most commonly the objective outcome is measured by a pad test, a cough stress test and also by urodynamic examination. Subjective outcome is evaluated by patient self-assessment, voiding diaries, patient satisfaction and validated general or condition-specific quality of life questionnaires [Lose *et al.* 2001, Dmochowski and Scarpero 2007, Ghoniem *et al.* 2008].

Pad test

A one hour pad test was described in 1981 to obtain information on the severity of urinary incontinence. Continent women had less than a 1 g/h increase in pre-weighed pad weight and incontinent women had on average a 12.2 g/h increase [Sutherst *et al.* 1981]. Various kinds of pad tests have later been described. The tests can be divided into short-term tests (<1 h−2 h) performed in a clinical setting, and long-term tests (12-h, 24-h or 48-h) performed by the patients during normal daily living. In 1983 the ICS suggested the use of the 1-h pad test for quantification of urine loss, but subsequently it was shown to be highly dependent on bladder volume and the negative predictive value of the test was low [Abrams *et al*. 1988, Lose *et al*. 1988, Siltberg *et al.*1997, Ryhammer *et al*. 1999]. In one study longer 24-h and 48-h pad tests were evaluated and the study showed that the reproducibility of home pad tests was good [Versi *et al.* 1996]. Pad tests of longer duration seem to be more reliable and accurate and the Fourth International Consultation on Incontinence therefore recommended the use of the 24-hour pad test for the evaluation of urinary incontinence [Karantanis *et al*. 2005, Abrams *et al*. 2010]. The 24-h home pad test has been studied in asymptomatic women, in whom the median weight gain was found to be 4.0 g (range 0−10g) per 24 hours and the 99th percentile for "normal" pad weight increase was 8 g, which is commonly understood to be caused by perspiration and vaginal discharge. This upper limit is frequently used as the sign of a "negative" pad test result [Kromann-Andersen *et al*. 1989].

Cough stress test

The cough stress test is widely used as part of the clinical assessment of patients having symptoms of stress urinary incontinence. If it is performed when the patient's bladder is subjectively full, the test is highly reliable [Swift and Yoon 1999]. Filling of the bladder is either spontaneous, in which case the patient is asked to urinate 2 hours before the test and then to drink two cups of water, after which the bladder is scanned ultrasonographically to check that there is a volume of 250−300 ml before the stress test, or the bladder is filled with 300 ml saline through a catheter. The patient is placed in a lithotomy position and is then asked to make vigorous coughs while the physician observes the external urethral meatus and if fluid is escaping, the test is positive. If the

test is negative in the lithotomy position, a retest is performed in a standing position [Ghoniem *et al*. 2008]. The cough stress test has been assessed in urodynamic studies and it has demonstrated good sensitivity and specificity in the diagnosis of SUI [Swift and Ostergaard 1995].

Invasive urodynamic testing

Evaluation criteria necessary to diagnose SUI have been under debate. Invasive urodynamic investigations have previously been regarded as gold standard methods of diagnosis. Invasive urodynamic investigations are expensive, time-consuming and unavailable in many centres. An international panel of experts, however, still recommends urodynamic investigations for all patients who require surgical treatment of SUI. This recommendation is made despite the knowledge that detrusor overactivity may not be demonstrated during urodynamic examinations and that detrusor overactivity may be seen in asymptomatic patients [Chapple *et al*. 2005].

A study of the cost-effectiveness of preoperative testing for SUI revealed that invasive urodynamic examinations did not improve the effectiveness of treatment, particularly if the prevalence of stress incontinence in the suspected patient population exceeded 80%. In this study it was shown that basic office assessment was suitable for otherwise healthy women of ≤65 years of age with predominantly stress urinary incontinence symptoms. The protocol included detailed medical history, physical examination, urine analysis, a cough stress test and measurement of post-void urine volume [Weber *et al.* 2002].

In the most recently published report on multichannel urodynamic evaluation prior to surgery it was concluded that urodynamic evaluation is recommended before surgical treatment of SUI, if there is clinical suspicion of voiding dysfunction. Otherwise, urodynamic examination might be unnecessary for women who complain only of SUI [Mourtzinos 2010].

Health-related questionnaires − condition-specific and general

There are a number of questionnaires that are used to assess the subjective success of incontinence treatment. The IUGA has recommended several validated questionnaires for clinical studies to be used in the treatment of stress urinary incontinence [Ghoniem 2008]. These include condition-specific questionnaires such as the Urogenital Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ), both of which were originally designed for assessment of incontinence in a female population [Shumaker *et al*. 1994]. The authors of these questionnaires later studied which subsets of items best approximated the scores found in the long-form versions, and thus short forms (UDI-6 and IIQ-7) were developed [Uebersax *et al*. 1995]. These short-form questionnaires are commonly used in clinical trials. The King's Health Questionnaire is a validated 21-item measure of health-related quality-of-life, originally designed for incontinent women, but reliable and valid for both genders [Kelleher *et al*. 1997, Okamura *et al*. 2009].

Incontinence and other urogynaecological conditions can have a negative impact on all quality-of-life domains. General health-related questionnaires vary substantially in their content and in their specificity as regards incontinence. Efforts to find the best instruments to compare scores across populations and also in connection with different diseases are ongoing. The SF-36 questionnaire is the most common general health-related quality-of-life instrument which is self-administered, and it is used to assess quality of life in eight areas of health: physical function, social function, pain, emotional well-being, energy, general health perceptions and role limitation due to 1) physical and 2) emotional problems [Ware and Sherbourne 1992]. The EuroQol Group first met in 1987 and later developed the EQ-5D questionnaire, which is not aimed at one particular disease or treatment, but is designed for use across a wide range of health-related domains. It is self-completed by the respondent and they describe their own health state in five areas: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. In one question the general level of health over the past 12 months is compared with the state of health today. In addition to these there is a thermometer-like scale for the responder to indicate how good or bad their current state of health is [Brooks 1996].

For almost three decades there has been a wide use of two urinary incontinence specific questionnaires in Finland, the Urinary Incontinence Severity Score (UISS) and the Detrusor Instability Score (DIS). The first of these has been proved to be valid, reproducible and responsive to the treatment of urinary incontinence in women [Stach-Lempinen *et al.* 2001] and the second has been validated for use in an outpatient urogynaecological setting [Klovning *et al.* 1996].

Validity of assessment

The internal validity of a study reflects whether or not the results of the study are valid for the original study population, or whether they suffer from a systematic error. Currently, common opinion is that randomized controlled trials (RCTs), systematic reviews and meta-analyses are generally the most reliable methods of determining the effects of treatment. RCTs must be internally valid, so that their design and execution minimize the possibility of systematic errors. External validity is a more complex concept. It reflects whether or not the results of a study are valid as regards the source population, which might be different from the study population. For example, the geographic, ethnic and socio-economic characteristics of the source population might differ from those of the study population. Simplified external validity or generalizability means that the result of a RCT should be relevant to clinical practice, so that the result of a treatment is replicated when applied to a definable group of patients in a clinical setting [Dekkers *et al.* 2010, Rothwell 2010].

Results of the most commonly used traditional surgical techniques for treatment of stress urinary incontinence

A variety of surgical techniques have been described for the treatment of SUI. The problem with older reported studies is the lack of standardized outcome measures, loss of patients to follow-up and the lack of long-term follow-up.

Pubovaginal sling procedures

Giordano described possibly the first sling operation in 1907. The gracilis muscle was used to encircle the urethra and acted as a sphincter [Giordano 1907]. In 1910 Goebell modified the technique, developing a suburethral sling using the pyramidalis muscles and Frangenheim further modified the technique in 1914 by leaving a strip of overlying rectus fascia on the pyramidalis muscles [Goebell 1910, Frangenheim 1914]. Stoeckel included a vaginal approach in order to avoid bladder injury, and performed a kind of anterior repair [Stoeckel 1917]. The Goebell-Frangenheim-Stoekel procedure involved the pyramidalis muscles, elongated by a strip of the rectus muscle fascia, being used to create a sling (placed from above) beneath the urethra after plication of the muscular structures around the urethra [Aldridge 1942]. In 1933 was reported on a technique in which a strip of fascia lata was used instead of the muscle-fascia combination. In 1942 Aldridge described a rectus fascia sling in which two strips of rectus fascia were sutured in the midline below the urethra [Aldridge 1942].

In 1978 McGuire and Lytton reintroduced a pubovaginal sling procedure for stress incontinence patients who had a low pressure urethra ($\leq$10 cmH_2O), most of whom had had previous incontinence operations. They described 52 patients, of whom 42 had had a prior operation for stress incontinence and 29 had uninhibited detrusor contractions simultaneously with SUI. They used a combined abdominal and vaginal approach and created a sling of the fascia of the rectus abdominis and external oblique muscles. The cure rate of stress incontinence reported for this procedure was 96% after a mean follow-up period of 2.3 years (range 10 months to 6 years). In 20 of the 29 patients who had had uninhibited detrusor dysfunction preoperatively, detrusor dysfunction could not be provoked postoperatively [McGuire and Lytton 1978].

During the latter part of the 20th century sling procedures were mostly used for treatment of patients with severe incontinence and for those with recurrent incontinence and/or intrinsic sphincter deficiency and they were avoided for treatment of primary SUI. This was mainly because the sling procedures were associated with severe adverse events and morbid conditions such as prolonged urinary retention, urinary tract infections and secondary detrusor instability [Sarver and Govier 1997].

Open bladder neck suspension procedures

In 1949 Marshall, Marchetti and Krantz developed a vesico-urethral suspension, later called the MMK procedure, in which three chromic catgut sutures were placed in the paraurethral tissue and a fourth at the level of the bladder neck. The sutures were anchored to the periosteum of the pubic bone to elevate the neck of the bladder and compress the proximal urethra during an increase in abdominal pressure [Marshall *et al.*1949]. The first reported overall success rate of this operation was 84% [Marchetti *et al.*1957]. A retrospective, subjective evaluation of the results of the MMK procedure revealed a declining cure rate from 81% (6 months after the operation) to 28% (10 years postoperatively) [Czaplicki *et al.*1998]. In a clinical review of the MMK procedure the overall success rate was of 86% in 2712 cases. The overall complication rate was 21% and the most significant complication of this procedure was osteitis pubis, seen in 2.5% of the patients [Mainprize and Drutz 1988]. To avoid this complication, in 1958, Burch described a procedure in which Cooper's ligament was the fixation point for suspending sutures.

In 1968 Burch reported on a series of 168 patients with a follow-up period of 10 to 60 months, in which only 7% of the patients were complete or partial failures. The most challenging complication was enterocele, occurring in 7.6% of the cases [Burch 1968]. The overall cure rate associated with open colposuspension was later reported in a Cochrane review to be between 69−88% within the first year of follow-up and approximately 70% at five years [Lapitan *et al.* 2009]. In a randomized study Burch colposuspension and the pubovaginal sling procedure were compared. The success rate specifically referring to stress incontinence was only 49% after 24 months of follow-up in connection with Burch colposuspension [Albo *et al.* 2007]. In the same study the rate of serious complications was 10% as regards colposuspension and the rate of minor

complications was as high as 47%, urinary tract infection (UTI) accounting for two thirds of them [Albo *et al.* 2007]. Galloway *et al.* had previously published a report on complications related to Burch colposuspension. After a mean period of 4.5 years of follow-up only 44% of the patients were dry and free of complications [Galloway *et al.* 1987]. Even though Burch colposuspension has been satisfactory for the treatment of SUI, the complications associated with the procedure have been notable. Open Burch colposuspension was regarded as the gold standard of female stress urinary incontinence surgery until recently, since when the Tension-free Vaginal Tape procedure has largely replaced it.

Follow-up studies (five years or more) of open Burch colposuspension are shown in Table1.

Table 1. Studies on long-term (≥5 years) results of open Burch colposuspension

Authors	Study design	Number of patients	Patient material	Follow-up time, years (range)	Subjectively cured + improved	Objectively cured
Eriksen *et al.* 1990	Retrospective	79	SUI or MUI	5	52% cured (completely free of LUTS)	67% cured (symptomfree, negative stress test and positive UCP during stress provocation (if done)
Feyereisl *et al.* 1994	Retrospective	87	Primary SUI (60%) secondary (40.2%)	5−10		82%, (symptom-free, stress test negative and positive UCP during stress provocation)
Alcalay *et al.* 1995	Retrospective	109	SUI or MUI, primary 71%, secondary 29%	13.8 (10−20)	72.5% cured of SUI	69% no stress incontinence in clinical examination and uroflowmetry
Bergman and Elia 1995	Randomized	33	Primary SUI		Combinated with objective cure	82% no symptoms of incontinence and no loss of urine on cough profile during UCM

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Authors	Study design	Number of patients	Patient material	Follow-up time, years (range)	Subjectively cured + improved	Objectively cured
Drouin *et al.* 1999	Retrospective	79	SUI and MUI, primary 66%, secondary 34%	7.6 (5.3−10.8)	44% cured + 25% improved	-
Kulseng-Hanssen and Berild 2002	Retrospective	82	SUI and MUI	7.5 (5−10)	27% no + 41% occasional	73% (stress test) 75% (24-h pad test)
Kjølhede 2005	Retrospective	192	SUI and MUI	14 (10−18)	19% cured 25% improved	-
Ward and Hilton 2008	Randomized	72	Primary urodynamic SUI	5	70% cured of SUI 46% no leakage in any circumstances	90% cured (1-h pad test), when last observed result carried forward (LOCF), 69% cured

Vaginally approached incontinence operations

In 1914 Kelly and Dumm published an article on the treatment of stress urinary incontinence. Their theory of the cause of SUI was "vesical neck funneling", which they hypothesized was caused by loss of elasticity or normal tone of the urethral and vesical sphincter. Their correcting procedure of was plication of the relaxed tissues of the vesical neck and anterior vaginal wall with interrupted mattress sutures. They described in detail a case series of 20 patients, follow-up of whom in many cases was more than 2 years. The immediate result on discharge from hospital was 90% (cured or improved), but the results decreased to 65% after longer follow-up [Kelly and Dumm 1914]. Another prominent surgeon at that time was Kennedy, who also suggested that injury of the urethral sphincter is the principal aetiological factor behind SUI and he made his own modification of the "Kelly plication" [Kennedy 1937]. The Kelly technique was easy to learn and the results were the best at the time. The procedure was rapidly adopted and this form of anterior colporrhaphy became the standard treatment for over 60 years. The long-term success rates of anterior colporrhaphy for treatment of SUI have been 31−38% after 5−10 years of follow-up [van Geelen *et al.* 1988, Bergman and Elia 1995, Demirci *et al.* 2002]. The rate of complications has been poorly reported according to the results of a Cochrane review [Glazener and Cooper 2001]. The described complications include, for example, bladder perforation, haemorrhage, urinary retention, UTIs and wound infections. In one study 16% of the patients had perioperative complications, of which 80% were UTIs [de Tayrac *et al.* 2002].

Needle suspensions

In 1959 Pereyra launched what was probably the first less invasive form of surgery for incontinence. He used a special cannula through which stainless steel wires were transferred from the vagina to the suprapubic area without opening the abdominal cavity. He used a Foley catheter balloon to locate the urethra and bladder neck and to move these tissues away from the course of the special cannula in order to avoid injury of these tissues during the operation. The objective cure rate assessed by a stress test (coughing and straining with a filled bladder), as well as the subjective cure rate was 90% after a 14-month follow-up period [Pereyra 1959].

In 1973 Stamey *et al.* introduced endoscopic control of placement of the sutures at the bladder neck. The principle of this procedure was to raise the bladder neck to a position behind the symphysis pubis by passing monofilament nylon threads through the anterior rectus fascia into the vaginal incision, at the site of which the threads were brought through a 1 cm Dacron tube, with a 5 mm diameter, and then back through the rectus fascia. The results among 44 consecutive patients showed cure of 41 (93%) and the evaluation pre- and postoperatively involved lateral view cystograms and cholinergic sensitivity tests [Stamey *et al.* 1975]. Later, Stamey reported results among 203 consecutive patients. The cure rate was 91% after a minimum of 6 months' follow-up and almost one third of the patients were followed up for over four years [Stamey 1980].

In 1981 Raz introduced his modified bladder neck suspension procedure with patient material of 100 consecutive women suffering from SUI. The results were classified as excellent in 96% of the patients, in spite of a high rate of self-administered intermittent catheterization, which was needed for 55% of the patients [Raz 1981].

Needle suspensions increased in popularity, because they were the first less invasive procedures for the treatment of SUI and numerous modifications were introduced, with only short follow-up times. In 1997 long-term results of the Stamey needle suspension procedure were published with a cure rate of 32% and a rate of improvement in 39% after a median of 7 years of follow-up. It was found that cure rates declined with time [Christensen *et al.* 1997].

Initial reports were not focused on complications, but widespread use of needle suspensions revealed delayed side-effects mainly related to the Dacron tubes or suture materials. Persistent local side-effects have been reported in 9% of patients after Stamey needle suspension. Urinary urgency has been recorded in as many as 70% of patients after this procedure [Clemens *et al.* 1998].

Development of the TVT and the other mid-urethral sling procedures

Traditional incontinence operations were aimed at correcting the anatomical position of the bladder neck and the proximal part of the urethra. As early as in the 1970's and 1980's the results of a series of different research projects suggested that the more distal part of the urethra might be of great importance in the continence mechanism [Ulmsten 1982, Westby *et al.* 1982, Asmussen and Ulmsten 1983].

In the early 1990's the "integral theory" was introduced. This theory primarily provided a basis for the development of a new surgical procedure for treatment of female SUI. The procedure was intended to reinforce the pubo-urethral ligaments and support the mid-urethra instead of suspending the urethra as high as possible. The new procedure, performed under local anaesthesia, through a vaginal approach as a day-care operation was initially called the Intra-Vaginal Slingplasty (IVS) procedure [Ulmsten and Petros 1995]. A problem with the first-developed IVS procedure was tissue rejection of the tape material (Gore-Tex and Mersilene) in 8−10% of the cases [Ulmsten *et al.* 1996]. A first attempt was to create new pubo-urethral ligaments by inserting two free tapes paraurethrally instead of implanting a permanent sling around the urethra. In comparison, the results of a permanent u-shaped sling were better than the two para-urethral free tapes. The procedure was developed further using a monofilament, macroporous polypropylene tape material and the final Tension-free Vaginal Tape procedure was presented in an article in the International Urogynecology Journal in 1996 [Ulmsten *et al.* 1996]. Encouraging findings in this first report were minimal intra- and postoperative complications with no rejection of the special polypropylene tape. The tape was covered with a plastic sheath to be removed after correct positioning of the tape, thus preventing contamination and infection. The cure rate was high and the operating time was less than half of the time needed for Burch colposuspension. Local instead of general anaesthesia allowed same-day discharge, which has made a great change in incontinence surgery [Ulmsten *et al.* 1996].

Further development of the mid-urethral procedure by different surgeons was aimed at minimizing the risk of complications potentially occurring because of the partially blind passage of the tape retro-pubically. Retropubic placement of the mid-urethral tape had been associated with a risk of bladder perforation at rates between 2.7% and 7.3%

[Tamussino *et al.* 2001, Kuuva and Nilsson 2002, Agostini *et al.* 2006]. The intrapelvic route of the retropubic procedure had revealed rare cases of more serious complications (injuries to blood vessels, bowel and nerves) [Agostini *et al.* 2006]. To avoid these complications Delorme developed an outside-in transobturator route of insertion of the tape, a Trans-Obturator Tape (TOT). It was first launched as the UraTape®, which was a non-woven, non-elastic polypropylene tape with a 15 mm-long central (suburethral part) silicone-coated section. The silicone coat was added in order to limit retraction of the polypropylene material and to establish a barrier to extension of periurethral fibrosis [Delorme 2001]. The first 1-year follow-up results of this operation were promising, with around 90% cured and no intra-operative complications [Delorme 2004]. It was later found that the rate of erosion occurring with the type of mesh used was unacceptably high and the device was withdrawn from clinical use. Product modification continued and new outside-in transobturator kits were soon available. All of these later commonly used synthetic TOT kits utilize type I polypropylene mesh and the most widespread example of these is the Monarc® TOT [Roth *et al.* 2007].

In 2003 de Leval introduced the Tension-free Vaginal Tape Obturator (TVT-O), also to avoid injury of intra-abdominal organs and the urethra. The TVT-O procedure is an inside-out procedure, in which the tape is passed from a vaginal incision through the obturator foramens, towards the thigh folds, in contrast to the outside-in procedure starting at the thigh folds and aiming at the mid-urethral area at the vaginal incision. The material of the TVT-O tape is the same type of polypropylene as in the TVT procedure. The first report on the results of the TVT-O operation did not include rates of cure, but was focused on per-operative intra-abdominal complications, of which there were none. One patient had a vaginal wall perforation during the operation and 16% of the patients complained of moderate pain or discomfort in the thigh folds directly after the operation. After one month of follow-up 2.8% of the patients had complete urinary retention and one patient had minor vaginal erosion [de Leval 2003].

The promising results of the original TVT procedure resulted in an intense competition and many modifications of mini-invasive slings were put on the market. Evidence of the efficacy and safety of these new slings were in many cases limited in quality and quantity. In 2001 a modification of the retropubic TVT procedure called the Supra-Pubic Arc (SPARC) sling procedure was introduced. The SPARC® needles were introduced from above through abdominal incisions towards the mid-urethra. In a randomized study

published in 2006 in which TVT and SPARC® were compared, no statistically significant difference in objective cure rate at 6 weeks was found, but fewer patients were subjectively cured in the SPARC® group (76.5% *vs.* 87.1%) than in the TVT group and more patients in the SPARC® group had voiding difficulties (18.2% *vs*. 8.1%) [Lord *et al.* 2006].

A transobturator outside-in method, the Mentor ObTape™ procedure was introduced in 2003. The tape material of the Mentor ObTape™ is made from polypropylene, but the pore size is smaller (50 µm) than in the type I polypropylene meshes and the tape is prepared through a heat-welding process, which may alter its permeability to cell and vascular in-growth. In 2006 marketing of this tape was stopped because of an unacceptably high extrusion rate (13.4%) [Yamada *et al.* 2006].

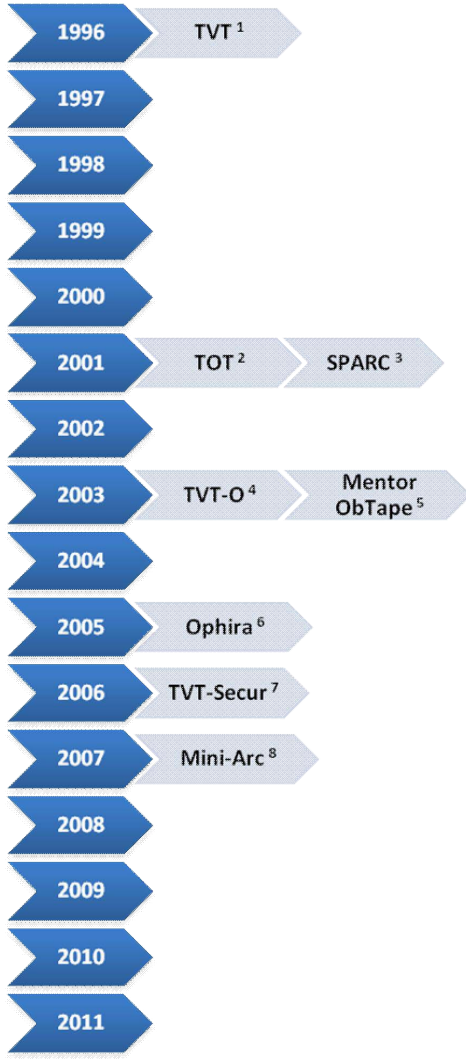
The TVT-Secur™ operation was designed in 2006 as a single-incision procedure in order to further minimize adverse events by shortening the tape to 8 cm. The tape ends could be anchored either in the internal obturator muscle or the urogenital diaphragm [Neuman 2007]. An early efficacy report on this procedure revealed its inferiority compared with the classical TVT procedure, the cure rate being only 60% [Alinsod 2009].

The Mini-Arc® sling, introduced in 2007, is also a single-incision procedure for stress incontinence. The results of a multicentre prospective study were published in 2010 and showed a cure rate of 90.6% after 12 months of follow-up [Kennelly *et al*. 2010].

Recently a meta-analysis comparing single-incision slings with retropubic and obturator slings was published. It revealed that single-incision slings perform inferiorly when compared to TVT and TVT-O procedures [Abdel-Fattah *et al.* 2011]. The results of long-term follow-up and appropriately powered randomized comparative trials are still awaited.

Evolution of mid-urethral slings is presented in Figure 1.

Figure 1. Evolution of mid-urethral slings



1. Ulmsten *et al.* 1996
2. Delorme 2001
3. Deval *et al. 2003*
4. de Leval 2003
5. Yamada *et al.* 2006
6. Palma *et al.* 2008
7. Molden and Lucente 2008
8. Moore *et al.* 2009
9. Meschia *et al.* 2011

Results of surgical treatment of recurrent stress urinary incontinence

Traditional surgery for recurrent stress urinary incontinence

Traditional incontinence operations have been performed after one or several previous incontinence operations. The success rate of Burch colposuspension after 5−10 years of follow-up in a group of patients with a history of one or two previous operations was 83.3% and 81.8%, respectively [Feyereisl *et al.* 1994]. In an earlier review, objective results of treatment of recurrent incontinence were reported. For colposuspension the mean continence rate was 83%, for needle suspension without endoscopy (Pereyra) 75%, for endoscopic needle suspension (Stamey) 86%, for bladder neck sling 86% and for periurethral injections 58% [Jarvis 1994]. In a small study a repeat pubo-vaginal sling procedure had been performed in 14 patients with recurrent incontinence after a primary suburethral sling procedure [Petrou and Frank 2001]. Based on Blaivas-Groutz anti-incontinence scoring [Groutz *et al.* 2000] 50% of the patients were objectively cured (score 0) and 36% improved (score 2−4). Subjectively, 86% considered themselves cured or improved [Petrou and Frank 2001]. In another small study in which four different surgical treatments for recurrent SUI were compared, an 81% objective cure rate in connection with Burch colposuspension was reported after one previous incontinence operation [Amaye-Obu and Drutz 1999].

Mid-urethral tape procedures for recurrent stress urinary incontinence

The efficacy of the original retropubic TVT procedure has been studied when performed after unsuccessful traditional incontinence operations. The results of such studies are presented in Table 2. There is only sparce evidence of the efficacy of other mid-urethral tape procedures as reoperations after traditional incontinence surgery. In a novel report on the transobturator tapes TVT-O and TOT-Aris in the treatment of recurrent stress incontinence, the objective cure rate after 1 year of follow-up was 76.5%, with no difference between procedures [Abdel-Fattah *et al.* 2011].

Table 2. Objective results of the TVT procedure for recurrent stress urinary incontinence

Authors	Number of patients	Follow-up time, months (range)	Objectively cured %
Azam *et al.* 2001	67	12	81% (no leakage in UCM+1-h pad test, patient satisfied and dry)
Rezapour and Ulmsten 2001	34	48 (36−60)	82% (stress test + 24-h pad test + patient satisfaction >90%)
Nilsson and Kuuva 2001	45	16 (6−24)	84% (stress test + 24-h pad test)
Debodinance 2002	17	12	70% (urodynamic examination)
Lo *et al*. 2002	41	12	82.9% (1-h pad test + stress test during upp)
Kuuva and Nilsson 2003	51	25 (24−60)	89.6% (stress test +24-h pad test)
Liapis 2004	33	20.5 (12−29)	70% (1-h pad test)
Ala-Nissilä *et al.* 2010	60	2	85% (stress test + patient reported no leakage on straining)

upp = urethral pressure profile

Postoperative symptoms of urgency in patients with urinary incontinence

Urgency is a complaint of a sudden compelling desire to pass urine, which is difficult to defer. The term overactive bladder (OAB) syndrome (previously urgency syndrome) includes urinary urgency, usually with frequency and nocturia, with or without urgency urinary incontinence. These definitions are from the newest joint report on the terminology of female pelvic floor dysfunction [Haylen *et al*. 2010].

During the past few decades the terminology has changed and it has also varied between urologists and gynaecologists. This inconsistency has led clinicians and researchers to develop their own criteria for defining bladder storage problems when evaluating the outcome of treatment options. The terminology and definitions of urgency from one study to another have been very variable and therefore the results are difficult, if not impossible, to compare with each other. In many studies the number of concomitant procedures performed at the same time as incontinence surgery is substantial.

It has been estimated that 29−61% of women with incontinence suffer from a combination of both stress and urgency urinary incontinence symptoms [Segal *et al*. 2004]. In population-based studies the prevalence of urgency symptoms increases with increasing age [Hunskaar *et al.* 2004]. Urgency symptoms are progressive, and women with urgency without incontinence frequently later develop urgency urinary incontinence [Irwin *et al*. 2010].

The problem with population-based studies is that women, who have been treated and those who have not are included in the population. This might have an effect on the incidence and prevalence figures, even though most women do not seek help for incontinence [Hunskaar *et al*. 2004]. A question not yet answered is within how long a time period after incontinence surgery do new symptoms of urgency caused by the surgery appear? Does the increasing incidence of urgency after surgical treatment of stress incontinence represent a long-term effect of the procedure, or is the increase in urgency symptoms a result of aging or other medical conditions [Chaikin *et al.* 1998]?

Effect of traditional incontinence operations and mid-urethral tape operations on urgency and *de novo* urgency symptoms

Studies on the effects of different incontinence operations on urgency and *de novo* urgency symptoms are shown in Tables 3 and 4.

Table 3. Effect of Burch colposuspension and the traditional pubovaginal sling procedure (autologous rectus fascia) on symptoms of urgency

Authors	Number of patients	Follow-up time, years (range)	UUI/urgency		*De novo* urgency
			resolved	persistent	
Burch colposuspension					
Herbertsson and Iosif 1993	72	9.4 (8−12)	41%	59%	40%
Alcalay *et al.* 1995	109	13.8 (10−20)	20% of DI	80% of DI	14.7%
Langer *et al.* 2001	127	12.4 (10−15)	52%	48%	*de novo* DI 16.6%
Kjolhede 2005	190	14 (10−18)	-	-	36%
Albo *et al.* 2007	329	2	-	18%	3%
Ward and Hilton 2008	169	5	-	-	*de novo* urgency 5%, *de novo* UUI 4%
Kenton *et al.* 2009	293	6 weeks	-	29%	9%
Pubovaginal sling					
Chaikin *et al.* 1998	251	12, 36, 60, over 120	-	23%, 26%, 31%, 41%	3−5%
Cross *et al.* 1998	150	22 (6−42)	75%	25%	19%, after 3 months treatment 3%
Fulford *et al.* 1999	85	3	54%	46%	7.7%
Schrepferman *et al.* 2000*	84	27 (2−62)	51%	-	-
Albo *et al.* 2007	326	24	-	24%	3%
Kenton *et al.* 2009	318	1.5	-	41%	18%

* autologous rectus fascia or fascia lata

Table 4. Effect of mid-urethral sling procedures on symptoms of urgency

Author	Procedure	Number of patients	Follow-up time, months (range)	UUI/urgency		*De novo* urgency
				resolved	persistent	
Laurikainen and Kiilholma 2003	TVT	191 including 64 with MUI	17	60% UUI improved		4.8% UUI
Segal *et al.* 2004	TVT	98 including 65 with MUI	7 (1.5–12)	63% of UUI 57% of OAB	37% of UUI 43% of OAB	UUI 9.1%, OAB 4.3%
Lim *et al.* 2006	TVT-O	100 including 59% with urgency	12	-	35%	4.8%
Botros *et al.* 2007	TOT TVT SPARC	125 99 52	3-9	65% 48% 43%	-	8% 32% 19% (UUI)
Choe *et al.* 2008	TVT	132 including 73% with UUI	3	58.3% of UUI 23.5% of all OAB symptoms	41.7% of UUI 76.4% of OAB	-
Gamble *et al.* 2008	TVT TOT SPARC	59* 105* 29*	3 (1–17)	TVT 36% ** TOT 47%** SPARC 34%**	TVT 64%* TOT 53%* SPARC 66%*	-

* DO+, **DO-

Complications

Complications after Burch colposuspension and pubovaginal slings

Traditional incontinence operations are invasive operations, a fact which is reflected in high complication rates in both short- and long-term postoperative periods. These operations have been associated with significant risks of voiding dysfunction (2–27% after Burch colposuspension and up to 11% after pubovaginal slings), long-term self-catheterization (1.5–7.8% after pubovaginal sling), pelvic organ prolapse (2.5–27% following Burch colposuspension) and *de novo* urgency (8–27% following Burch colposuspension and 3–23% following pubovaginal sling operation) [Novara *et al.* 2010]. Other studies have revealed urgency symptoms in 29% [Alcalay *et al.* 1995] and urgency urinary incontinence in 23–41% of women after Burch colposuspension [Alcalay *et al.* 1995, Dietz and Wilson 2000].

Complications after mid-urethral sling procedures

Systematic national registers on complications of mid-urethral slings have been compiled in several countries, including Austria, Finland and France. These registers cover large numbers of patients and allow identification of the risks of even rare complications. The risk of bladder perforation during TVT surgery has varied between 2.7–7.3%. These national registers have also revealed very low risks of bowel perforation (0–0.04%), nerve injuries (0–0.07%) and major blood vessel injuries (0.03–0.07%) [Tamussino *et al.* 2001, Kuuva *et al.* 2002, Agostini *et al.* 2006].

In a recent update of a meta-analysis by Novara *et al.* it was shown that the retropubic route of mid-urethral sling placement was associated with higher rates of bladder perforations, vaginal injuries and haematomas than the obturator route of sling placement [Novara *et al.* 2010]. Another review, on the other hand, showed vaginal injuries and erosion twice as often in association with the transobturator route as with the retropubic route. In a subgroup analysis, cases of erosion were more often seen in the TOT group than in the TVT-O group. Symptoms of postoperative pain in the groin/thigh region are more common after obturator tape procedures than after the TVT procedure [Latthe *et al.* 2007].

Postoperative risks of suffering from UTI's vary greatly (0.4–32%) possibly dependent on the use or lack of use of urinary catheters postoperatively [Tamussino *et al.* 2001]. Voiding dysfunction seems to be more common in connection with a retropubic route than with a transobturator route [Latthe *et al*. 2007, Novara *et al*. 2008]. Well powered RCTs in which TVT and TVT-O procedures were compared, however, did not reveal any difference between the groups regarding voiding dysfunction [Meschia *et al*. 2007, Rinne *et al.* 2008]. Reported rates of *de novo* urgency symptoms also vary greatly, due to differences in definitions, in the initial study population and in operation techniques. Rates of between 2 and 23 per cent have been presented, with no difference in rates between retropubic and transobturator techniques [Latthe *et al*. 2007].

Reviews and meta-analyses combine studies and abstracts which mostly involve low numbers of patients and short periods (≤12 months) of follow-up. Studies on long-term complications after mid-urethral sling procedures are scarce. In one RCT concerning TVT versus colposuspension, the rate of complications at five years of follow-up was reported. The rate of lost-to follow-up in this report was significant (44%) and the results have to be interpreted with caution. The rate of prolapse surgery needed after incontinence operations was significantly lower (1.8%) in association with the TVT procedure than with colposuspension (7.5%) [Ward and Hilton 2008].

AIMS OF THE STUDY

The aims of this study were:

1. To evaluate the long-term efficacy and complications of the original minimally invasive, mid-urethral procedure (the Tension-free Vaginal Tape procedure) for treatment of female stress urinary incontinence.

2. To study the success of a repeat TVT procedure after long-term follow-up and to evaluate the reasons for failure in cases of unsuccessful outcome of the primary Tension-free Vaginal Tape procedure in these cases.

3. To compare the rates of cure and complications in the TVT procedure and in a newer modification of the operation, the TVT-O procedure, in the treatment of stress urinary incontinence.

4. To study the effects of the TVT and the TVT-O procedures on the prevalence of urgency symptoms over time.

MATERIAL AND METHODS

Patient populations

The Study I population consisted of 90 consecutive women who had urodynamically proven SUI. Three Nordic centres, one in Finland (Helsinki University Central Hospital) and two in Sweden (Danderyd Hospital in Stockholm and Uppsala University Hospital), participated in this prospective observational trial. The TVT procedures were carried out between January 1st 1995 and October 15th 1996 by experienced surgeons. The Ethics Committees of all three centres approved the study and informed consent was obtained from each patient. Patient characteristics and the age distribution of the cohort are presented in Table 5.

Table 5. Age distribution and other characteristics of the patient population (n = 90) in Study I

Patient population	
Age group	
<50	45.2%
51−60	28.6%
61−70	19.0%
71−80	4.8%
81−90	2.4%
Parity, median (range)	2 (0−4)
Symptoms of urgency preoperatively	29.4%
Duration of incontinence symptoms, years (range)	13 (2−25)

Inclusion criteria consisted of a history of stress incontinence, a positive cough stress test result performed in a lying and a standing position with a comfortable filled bladder (200−300ml), and urodynamic stress incontinence. Exclusion criteria are presented in Table 6.

Table 6. Exclusion criteria in Study I

Exclusion criteria
Prior incontinence surgery
Need for concomitant surgery
Detrusor activity during the urodynamic examination
Maximal urethral closure pressure <20 cm H_2O

Study II was a retrospective follow-up study and the patient population consisted of 26 patients among whom a repeat mid-urethral sling procedure had been performed at Helsinki University Central Hospital. The primary operations were performed between 1992 and 2002 and the repeat procedures between 1999 and 2004. Mean age at the last follow-up visit was 61±9 (SD) years. A previous traditional incontinence operation had been performed in 15% and previous hysterectomy in 50% of the women. Median parity was 2 (range 1−4) and mean BMI was 24±4 kg/m² at the time of the first mid-urethral surgery.

The patient population in Studies III and IV consisted of 273 women who were recruited to a randomized, multicentre trial in which two different mid-urethral sling procedures (the TVT and TVT-O procedures) were compared. Seven hospitals in Finland participated: four university hospitals and three central hospitals and the women were recruited between March 2004 and November 2005. The study was approved by the Ethics Committee of Helsinki University Central Hospital and written informed consent was obtained from each patient. Inclusion criteria were a history of SUI, an indication for surgical treatment of stress incontinence, a positive cough stress test result and DIS 7 or less. Exclusion criteria are presented in Table 7.

Table 7. Exclusion criteria in Studies III and IV

Exclusion criteria
Previous incontinence surgery
PVR >100 ml
Lower urinary tract anomaly
Current UTI or >3 UTI episodes within the past year
Urogenital prolapse of more than second degree (Baden-Walker)
BMI >35 kg/m²
Previous radiation therapy of the pelvis
Active malignancy
Anticoagulation
Haemophilia
Neurological disease that could be associated with bladder disorders
Use of anticholinergics/duloxetine
Inability to understand the purpose of the study
Immobilization

PVR = post-void residual, UTI = urinary tract infection, BMI = body mass index

Power analysis for samples was performed by assuming a 95% success rate for the TVT procedure and by assuming that a 10% difference in either success rate or rates of complications would be clinically important. With a 70% power to show a 10% difference, the sample size should be 260 patients with 130 in each arm. Randomization was performed using computer-generated random allocation in balanced blocks of four, and the investigators contacted an independent randomization centre located in Helsinki.

Methods

Study protocols

Pre- and postoperative evaluation in Studies I, III and IV included a gynaecological examination, a cough stress test, a 24-h pad test, post-void residual urine volume measurement, and use of a visual analogue scale (VAS 0−100) for assessment of degree of inconvenience. The Study I protocol also included preoperative urodynamic assessment. In Studies III and IV the following condition-specific quality-of-life questionnaires were used pre- and postoperatively: the Urinary Incontinence Severity Score, the Detrusor Instability Score, the Incontinence Impact Questionnaire−short form, and the Urogenital Distress Inventory−short form and the General quality-of-life was assessed by means of the EuroQoL-5D questionnaire. In Studies III and IV follow-up visits were scheduled at 2, 12, 36 and 60 months. In Study II the hospital records were retrospectively studied in connection with the primary mid-urethral operation and the time between the primary operation and reoperation. Evaluations at the follow-up visit after the repeat operation (TVT procedure) included a 24-h pad test, a cough stress test, careful gynaecological examination and post-void residual urine volume measurement. The following questionnaires were used to assess subjective outcome: UISS, DIS, UDI-6, IIQ-7 and VAS.

Surgical procedures

Tension-free vaginal tape

The tension-free vaginal tape operations in Studies I, III and IV and the repeat operations in Study II were carried out as described in detail by Ulmsten [Ulmsten 1996]. Commercial TVT kits were used (TVT Gynecare, Johnsson & Johnsson, Somerville, NJ, USA). The primary procedures in Study II were also retropubic procedures, but four different tape materials had been used (polypropylene, multifilament polypropylene, polytetrafluoroethylene, polyester). All tension-free vaginal tape operations were performed under local infiltration anaesthesia using prilocaine with adrenaline diluted to 0.25% and a single dose of prophylactic antibiotic (cefuroxime, 1.5 g, or metronidazole, 500 mg, intravenously) was given intra-operatively. Cystoscopy using 70-degree optics

was performed twice during the operation after each retropubic pass of the TVT needle in order to detect possible bladder injuries. Adjustment of the tape was performed using the cough stress test, with the bladder filled with 300 ml saline, allowing a few drops of fluid to escape on vigorous coughing in order to avoid retention. The bladder was emptied at the end of the operation by catheter.

Tension-free vaginal tape – obturator

The tension-free vaginal tape – obturator procedures in Studies III and IV were performed as described by de Leval [de Leval 2003]. This obturator technique is a so-called "inside-out" technique. All the patients were operated upon under local infiltration anaesthesia using the same dilution of anaesthetic and the same prophylactic antibiotics as in the TVT procedures. Commercial TVT-O kits were used (TVT Gynecare, Johnsson & Johnsson, Somerville, NJ, USA). Cystoscopy was performed once during the TVT-O procedure, and adjustment of the tape was done in the same manner as with the TVT procedure.

Objective outcome measures

Objective cure was defined as a negative cough stress test result in Studies III and IV. The criteria of objective cure in Study I were a negative cough stress test result and a negative 24-h pad test result (<8 g/24 h). In Study II cure was defined as overall cure including a negative cough stress test result, a negative 24-h pad test result (≤8 g/24 h) and a VAS score of ≤15 and improvement was defined as either the negative stress test or the negative pad test and the VAS ≤30.

Cough stress test (Studies I−IV)

A cough stress test was used as an objective evaluation method for SUI pre- and postoperatively. It was performed with a comfortably and spontaneously filled bladder (200−300 ml) in a semilithotomy position. The test result was interpreted as positive if urine leaked during repeat vigorous coughing.

Pad-weighing test (Studies I–IV)

A 24-hour pad weighing test was used as an objective evaluation method for urinary incontinence. The women used pre-weighed pads for a time period of 24 hours during normal daily activities. Used pads were weighed by the women with a scale received by mail from the clinic and the women marked the results on a specific form. The change in weight was used as an objective measurement of urine leakage.

Residual urine volume measurement (Studies I–IV)

At the follow-up visits in each study residual urine volumes, after normal spontaneous voiding, were measured by ultrasonography (Bladderscan®) and occasionally by catheterization.

Subjective outcome measures

Patient's Global Impression (Study I)

The Patient's Global Impression (PGI) of her continence status at follow-up visits was assessed by asking the women if they felt that they were cured of their incontinence, or if there was improvement, or if they felt that the treatment had failed.

Urinary Incontinence Severity Score (Studies I–IV)

The women completed the Urinary Incontinence Severity Score (UISS) questionnaire at each follow-up visit. The questionnaire consists of ten questions on the inconvenience caused by symptoms of incontinence (Appendix 1). The minimum score is 0 and the maximum score 20. The questionnaire has been proved to be valid and reproducible and the scores responsive to treatment of urinary incontinence in women [Stach-Lempinen *et al*. 2001].

Detrusor Instability Score (Studies I−IV)

The Detrusor Instability Score (DIS) questionnaire consists of ten questions related to symptoms of the lower urinary tract. Every question has three alternative answers scored 0−2 (Appendix 2). It was developed for the purpose of differentiating between urgency and stress urinary incontinence. The score range is between 0 and 20. The higher the score the more probable is the existence of urgency urinary incontinence. A score of seven or less is indicative of pure stress incontinence [Kauppila *et al*. 1982].

Visual Analogue Scale (Studies I−IV)

The Visual Analogue Scale (VAS) is formed by a line from zero to one hundred, where zero represents no urinary problems and one hundred unbearable urinary complaints (Appendix 3). The women were asked to place a mark at a point on the line which best described their current urinary problems. The VAS has been proved to be valid and reproducible and the scores responsive to treatment of urinary incontinence in women [Stach-Lempinen *et al*. 2001].

Incontinence Impact Questionnaire−short form (Studies I−IV)

The short form of the Incontinence Impact Questionnaire (IIQ-7) consists of seven questions related to domestic activities, social relationships, travel and physical activities (Appendix 4). The participant indicates how urine leakage affects their life, and the alternative responses are: not at all, slightly, moderately or greatly. A higher score means a lower quality of life. The formerly developed longer form included 30 questions [Shumaker *et al. 1*994]. The short form, however, has been found to be more practical in use and the scores obtained correlate well with those obtained by using the long questionnaire [Uebersax *et al.* 1995].

Urogenital Distress Inventory−short form (Studies I−IV)

The Urogenital Distress Inventory (UDI-6) is a six-question short form of a longer (19 questions) formerly developed questionnaire used to measure the impact of incontinence in women [Shumaker *et al.* 1994] (Appendix 4). The UDI-6 questionnaire can be divided into three parts: the first two questions are used to evaluate irritative symptoms (urinary frequency and urgency urinary incontinence), questions 3 and 4 concern stress symptoms and questions 5 and 6, voiding difficulty and pain [Uebersax *et al.* 1995].

EuroQoL-5D (Studies III, IV)

Current general health was evaluated by using the EuroQoL-5D questionnaire, which includes questions about mobility, self-care, usual activities, pain and discomfort, anxiety and depression. In addition to these questions a woman is asked to draw a line on a thermometer-like scale, which indicates the state of her health at a given moment [Rabin and de Charro 2003] (Appendices 5 and 6).

Statistical methods

The Statistical Package for the Social Sciences (SPSS version 15.0, Chigaco, IL, USA) was used for statistical analysis. Descriptive statistics used for continuous variables were mean, median and range and for categorial variables, frequencies. For analysis of continuous variables with normal distribution the independent-samples *t*-test and the paired-samples *t*-test were used to calculate statistical differences between and within the study groups. For continuous variables with non-normal distribution, Wilcoxon's non-parametric two-related samples test was used. The Chi-square test or Fisher's exact test were used for categorial variables. A p-value <0.05 was considered to indicate statistical significance.

RESULTS

Clinical outcome

Long-term results of the TVT procedure for stress urinary incontinence

The prospective eleven-year follow-up study of the TVT procedure (Study I) had a median time of follow-up of 141 months (range 127−160), which is an average of 11½ years. Of the original 90 women, 69 (77%) could be evaluated either in the clinic, according to the protocol, or by a home visit by urotherapist. The cough stress test was negative in 95.3% (61/64) of the patients, and 90.2% (55/61) had a negative 24-h pad test result. Objective cure was defined as a negative 24-h pad test and a negative stress test result and 90.2% of the women filled the criteria. Subjective cure was evaluated by means of PGI and 77% (53/69) of the women regarded themselves as cured, 20% (14/69) as improved and 3% (2/69) thought the treatment had failed.

Long-term efficacy of the TVT procedure as a repeat procedure

Twenty of the identified 26 women (77%) among whom a repeat mid-urethral sling procedure (using TVT) had been performed at the Department of Obstetrics and Gynaecology, Helsinki University Central Hospital, participated in the follow-up study. Overall cure was defined as a negative stress test and a negative 24-h pad test (≤8 g/24 h) and a VAS score of ≤15. Fifty-five per cent of the women fulfilled these criteria. The stress test was negative in 75% (15/20) of the women and the pad test was negative in 65% (13/20). Improvement was defined as a negative stress test or a negative 24-h pad test result with a VAS score of ≤30. Four women (20%) fulfilled these criteria. Five women (25%) were considered as failures both by objective and subjective criteria. The reasons of failure of the first operation could be separated into four different groups: tape material related (four women), operation technique related (six women), concomitant illness related (four women) and a group with no identifiable reason (six women).

Medium-term efficacy of the TVT and TVT-O procedures in a randomized context

In the randomized trial in which the TVT and TVT-O procedures were compared, objective cure was defined as a negative stress test result. Subjective cure was evaluated by means of the condition-specific questionnaires UISS, DIS, IIQ-7, UDI-6 and VAS.

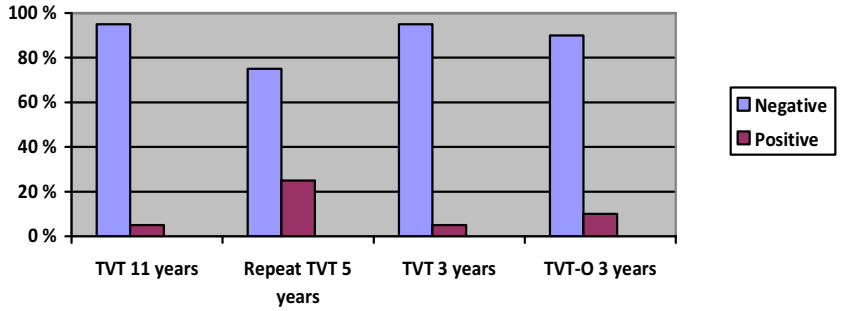


Figure 2. Rates of negative and positive cough stress test results in Studies I–III

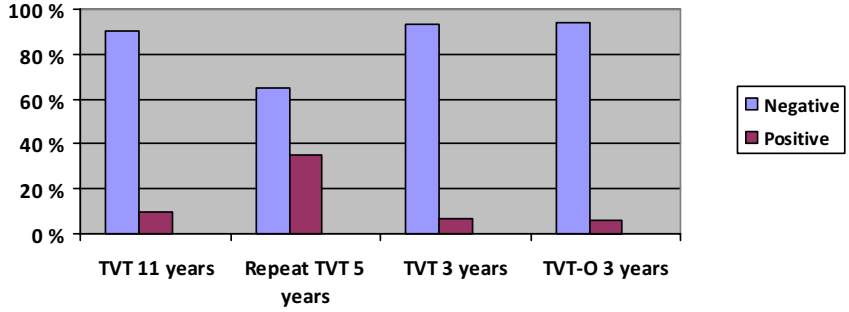


Figure 3. Rates of negative and positive 24-h pad test results in Studies I–III

Table 8. Results of the TVT and TVT-O procedures in Studies I–III

Years of follow-up	Study	Neg. 24-h pad test		Neg. stress test	
3 years	90.2%	95.3%	94.1%	94.6%	89.5%
5 years	Study II repeat TVT	65%		75%	
11 years	Study I primary TVT	90.2%		95.3%	

Subjective outcome

Quality-of-life questionnaires

Subjective outcome in Studies I–III measured by using VAS, UISS and DIS is presented in Tables 9 and 10. The women's quality of life pre- and 36 months postoperatively is presented in terms of IIQ-7 and UDI-6 results in Figure 4.

Table 9. Visual Analogue Scale (VAS) results

Study	Follow-up time, months, median (range)	Preoperative	Postoperative
I TVT	141 (127–160)	75 (35–100)	6 (0–90)*
II TVT	64 (34–100)	69 (10–100) before repeat operation	5 (0–86)**
III TVT	36	70 (11–100)	2 (0–91)***
III TVT-O	36	71 (18–100)	2 (0–87)***

*p<0.0001, **p<0.05, ***p<0.001

Table 10. UISS and DIS results

Study	Follow-up, months, median (range)	UISS		DIS	
		Preop.	Postop.	Preop.	Postop.
II TVT	64 (34−100)	60 (15−85)	5 (0−60)*	8.5 (1−16)	3.5 (0−12)**
III TVT	36	11±3	1.2±2.3*	5±2	3.0±2.6*
III TVT-O	36	11±3	0.9±1.8*	4±2	2.7±2.5*

*p<0.001, **p<0.05

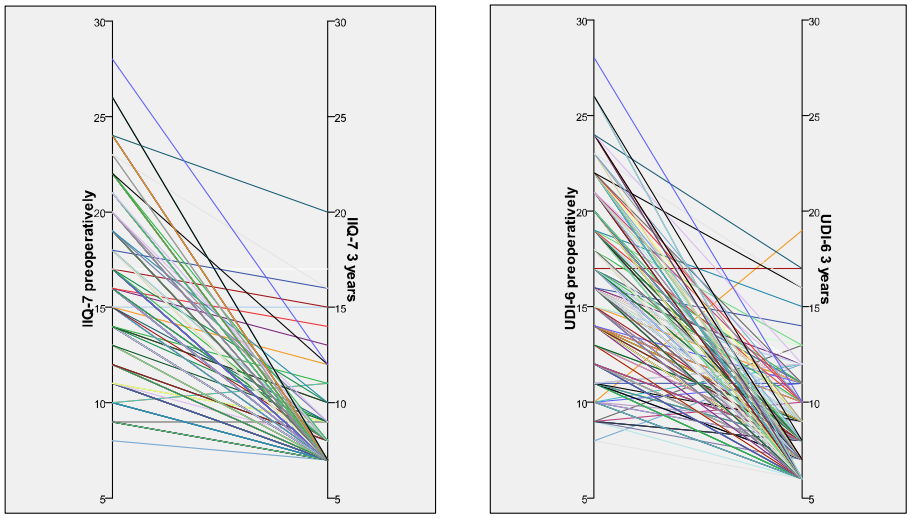


Figure 4. IIQ-7 and UDI-6 results in both treatment groups together preoperatively and 3 years postoperatively in Study III

Satisfaction with the procedure

The women appeared to have a positive image of mid-urethral tape procedures throughout the course of follow-up. The proportion of those, who would recommend the TVT procedure to a friend was 97% in Study I and 98.4% in Study III. The corresponding rate of satisfaction with the TVT-O procedure was 95.2% in Study III.

Complications

Long-term voiding difficulties associated with TVT surgery were rare. In Study I 93.1% of the women had a PVR urine volume of less than 100 ml and no patient needed catheterization. In Study II, after a repeat procedure two women (10%) had PVR urine volumes greater than 100 ml and catheterization was not needed for any of the women. In Study III, according to the UDI-6 question number 5, moderately or severely disturbing voiding symptoms were reported by four women (3.1%) in the TVT group, the PVR urine volumes of whom were, however, between only 0 and 45 ml. In the TVT-O group two women (1.6%) had voiding problems and their residual urine volumes were 15 ml and 19 ml. In Study III two women (1.5%) in the TVT group and four women (3.2%) in the TVT-O group had PVR urine volumes of more than 100 ml. One woman had had retention problems after the TVT-O operation and the tape had to be divided twice. Retention became resolved, but *de novo* urgency appeared.

In Study I new anticholinergic medication had been initiated in four women (5.8%) after the previous follow-up visit four years earlier. In Study III all women had a detrusor instability score of seven or less as an inclusion criterion. The *de novo* urgency rate was defined as new symptoms of frequency, or urgency of moderate or severe degree (UDI-6 results or a DIS score of >7) at the three-year follow-up visit. According to these criteria *de novo* urgency was found in 9.2% of the women in the TVT group and 5.6% in the TVT-O group with no statistically significant difference between the groups.

In Study III antibiotic treatment for UTIs had been needed for 15.4% of the women in the TVT group and 17.6% in the TVT-O group during the two years before the follow-up visit. Two women in the TVT group and five in the TVT-O group needed long-term prophylactic antibiotic treatment for recurrent UTIs.

In Study I no tape-related complications were found in careful gynaecological examination. In Study II four different tape materials had been used in the primary operation. Eight patients had had other than monofilament polypropylene tapes in their primary surgery (Teflon®, Mersilene® or multifilament polypropylene) and four of these slings had to be removed because of fistulation and infection. One case of tape exposure was found at the last follow-up visit after the repeat TVT procedure, which had been performed with a monofilament polypropylene sling. At the three-year follow-up visit,

of the women in Study III no exposure of the sling material in the vagina was found. One woman in the TVT-O group had experienced exposure of the sling 1 year after the operation and tape resection had been performed. This resulted in recurrence of SUI and a reoperation using a TVT procedure.

No rare or serious long-term complications were found in this study. Listed complications are given in Table 11.

Table 11. Complications in Studies I–III

Complications	**TVT 11 years**	**Repeat TVT**	**TVT 36 months**	**TVT-O 36 months**
PVR >100ml	6.9%	10%	1.5%	3.2%
Retention	0%	0%	0%	1 patient, division of the tape twice
Catheterization	0%	0%	0%	0%
De Novo urgency	-	-	9.2%	5.6%
Use of anticholinergic drugs	5.8%	5%	2.3%	0%
UTI	-	-	15.4%	17.6%
Recurrent UTI prophylaxis	-	-	1.5%	4.0%
Tape problems	-	1 tape exposure after repeat TVT	0%	1 tape exposure

DISCUSSION

Urinary incontinence is still a disguised problem in our society, regardless of the availability of modern treatment methods to improve or even cure this unfortunate situation. Long-term follow-up studies of incontinence surgery are scarce compared with short-term follow-up reports. The reason for this is obvious: long-term studies need most of all a dedicated person to carry forward the study protocol from year to year. Patients may cease participating in a long-term follow-up study and become lost-to-follow-up. The risk of this to happening has been observed to be higher in connection with the long-term follow-up of young adults with a curable disease [Small 1967].

Factors affecting long-term success

Long-term efficacy of surgical procedures is important, as a need for repeat operations in cases of declining efficacy has an impact on economic resources, which otherwise could be directed at different targets. There are no one hundred per cent successful incontinence operations and most probably no such procedures will be developed. A surgical procedure for treatment of SUI should be suitable for the majority of patients among whom surgery is contemplated. The concentrated training program for a new procedure very likely shortens the learning curve and improves the results. The success of a surgical procedure is correlated to the experience of the surgeon and the number of operations of a certain kind the surgeon has performed [Kuuva and Nilsson 2002]. Incontinence surgery should not be performed by all gynaecological surgeons in order to accumulate experience. On the contrary, incontinence surgery should be concentrated among persons who have the possibility to handle high numbers of surgically treated patients and who preferably stick to one or a few standard operations.

The 90% objective cure rate after 11 years of follow-up had not decreased when compared with those seen at short- and medium-term follow-up of the same population [Nilsson *et al.* 2001, Nilsson *et al.* 2004]. This study was the first publication on more than ten years of follow-up of the results of the TVT procedure. The subjective cure rate of 77% expressed by the Patient's Global Impression of cure is equal to or even better

than the reported subjective cure rates after the previous gold standard procedure, the open Burch colposuspension operation [Eriksen *et al.* 1990, Alcalay *et al.* 1995, Kjølhede 2005]. In the present study 93% claimed that they were dry in stress conditions. It was interesting to find that among those women who regarded themselves as cured (by way of PGI), the rate of medical conditions potentially affecting urinary symptoms was much lower than in women regarding themselves as improved or even as failures in connection with the operation. A recently published retrospective 11.5-year follow-up study of the TVT procedure showed similar cure rates (84% objective and 77% subjective) when compared with the present data [Olsson *et al.* 2010].

Long-term follow-up results of traditional incontinence operations have revealed that objective outcome is usually better than subjective outcome [Kulseng-Hanssen and Berild 2002, Ward and Hilton 2007]. The subjective outcome reflects the quality of life of the women treated by means of incontinence surgery and is currently regarded as a more appropriate way of looking at the results of treatment rather than by judging success on the rate of objective dryness. The lower subjective success rate may reflect long-term complications or adverse effects caused by the surgical procedure. Traditional incontinence operations, most of all pubovaginal sling procedures, have caused postoperative voiding dysfunction, outlet obstruction, and *de novo* urgency. These affect the quality of life of the women and their satisfaction with the procedure.

Repeat incontinence surgery and risk factors for failure

Regardless of good results of mid-urethra sling surgery, repeat operations are still needed. Knowledge of how different procedures can be carried out as repeat procedures and the expected results of such repeat procedures are important elements as regards patient selection and counselling.

Recurrent incontinence after traditional incontinence operations has been a frequently faced situation. In most of the studies reporting on the success of a repeat operation the primary surgical procedure for treating incontinence has mainly been anterior colporrhaphy. The results of traditional incontinence operations as repeat procedures have been reasonable good, but only a minority of the treated patients has been evaluated with long-term follow-up periods. Assuming lost-to follow-up patients to be either

failures or successes gives very different results and should be evaluated with special carefullness, especially they cannot be counted as successes.

In the present study the results of a repeat TVT procedure were not as good as the results of the TVT operation as a primary procedure, but the patient material was more complicated, with several of the identified risk factors for failure. Especially other medical conditions were considered to cause treatment failure in 20% of the patients. Materials other than monofilament, macroporous polypropylene tapes were used in the primary procedure and fistulation of these tapes was a reason for failure in 20% of the patients.

It is important to try to recognize late complications caused by artificial sling materials. Complications mostly require intervention and affect the results of the primary operation. This increases the costs for both the individual and society. In the present reoperation group, after five years follow-up, there was only one tape extrusion at the mid-line vaginal incision site, which might have resulted from defective healing. These results confirm the opinion that monofilament, macroporous, polypropylene tape is a safe material even during long periods of follow-up. A comparative study of mono- and multifilament tapes revealed an 11.8% vaginal extrusion rate for multifilament polypropylene tape (in IVS) and none in a TVT group with monofilament tapes [Prien-Larsen and Hemmingsen 2009].

Reasons for failure of mid-urethral tape procedures have been identified in several studies. Described reasons are a low-pressure urethra [Rezapour *et al.* 2001], mixed incontinence [Kulseng-Hanssen *et al.* 2008], prior incontinence operations [Meschia *et al.* 2007], age and obesity [Hellberg *et al.* 2007]. A weakness of the present study on the TVT operation as a repeat procedure is the small number of patients. The reason for the small number is partly to do with the high cure rates as a result of TVT surgery producing low numbers of patients with recurrent SUI.

Reasons for failure of traditional incontinence operations have also been evaluated. In a randomized controlled trial in which Burch colposuspension and pubovaginal slings were compared, predictors of failure of treatment of SUI were the severity of urge incontinence symptoms, the stage of urogenital prolapse and being post-menopausal without hormone therapy [Richter *et al.* 2008]. In another study the risk factors of failure were found to be age, postmenopausal status, obesity, detrusor instability, medium to

severe urogenital prolapse and previous incontinence surgery [Feyereisl *et al.* 1994]. Reports also indicate that an increased risk of surgical failure of traditional incontinence operations is a short functional length of the urethra and a low urethral closure pressure [Sand *et al.* 1987]. The identified risk factors of failure of incontinence surgery seem to be the same as regards both traditional incontinence surgery and mid-urethral sling surgery.

Development of new surgical procedures

Development of a new surgical procedure is a time-consuming commitment, starting from recognition of a need to improve existing treatment alternatives. Various findings and ideas are combined to create a theory that could serve as a basis for the development of new treatment modalities, like happened with the integral theory and the TVT procedure in early 1990's. A pilot study is conducted to test the potential of a new surgical procedure. In the case of a positive experience from a pilot study, prospective clinical research programmes to evaluate efficacy and acceptability of a procedure are initiated. If the new surgical procedure holds the promise of the pilot study, the next step is comparison of the new treatment with a generally accepted treatment within a randomized controlled trial. Unfortunately, these steps are often forgotten or deliberately skipped. This is currently possible because surgical procedures and devices used in surgery are not subject to the same strict regulation governing the development and marketing of pharmaceutical products. These circumstances allow marketing departments the opportunity to promote a new surgical procedure in terms of being more efficient, easier and quicker to perform and perhaps associated with a lower risk of adverse effects than established surgical procedures, without the backup of good quality clinical studies.

The favourable initial experiences with the first retropubic mid-urethral sling procedure, the TVT operation, evoked widespread interest in developing various modifications of the TVT procedure. The main purpose of the development of a trans-obturator approach was to minimize the risk of serious complications potentially occurring due to the blind passage of the TVT instrument retropubically [Delorme 2001]. The fact that a tape placed through the obturator membranes results in a more horizontal passage was thought

to diminish postoperative voiding difficulties. In the present study no serious mid-term complications of the TVT or the TVT-O procedures were found. Moderately or severely disturbing voiding problems were rare after both the TVT and the TVT-O procedure at the three-year follow-up visit. Hence long-term voiding problems appear to be rare after both the TVT and TVT-O procedures. In a recent review article by Ogah *et al,* however, it was found that voiding dysfunction was seen at a lower rate in connection with the obturator route than with the retropubic route at twelve months of follow-up [Ogah *et al.* 2011]. We found no reports on comparison of the rate of voiding difficulties between TVT and TVT-O groups with a longer period of follow-up than in the present study.

Prevalence of urgency symptoms associating with incontinence surgery

Symptoms of urgency, which are part of the OAB symptom cluster, appear to represent a dynamic condition. In a longitudinal population-based study carried out in Sweden the same women were assessed in 1991 and again in 2007 and the overall incidence rate for urgency was 20% and remission rate 43%, respectively [Wennberg *et al.* 2009]. In the same study the prevalence of urgency during the observation period increased from 17% to 26% [Wennberg *et al.* 2009].

The possibility of remission of urgency symptoms after traditional incontinence surgery has been less brought forward, possibly because attention has mainly been paid on the cure of stress urinary incontinence and on the occurance of *de novo* urgency symptoms and because mixed incontinence has been a common exclusion criteria. Some of the studies, however, have revealed resolution of urgency symptoms or UUI in 52−75% of patients [Cross *et al.* 1998, Langer *et al.* 2001]. Mid-urethral slings have been reported to resolve symptoms of urgency or UUI in 42−65% of patients [Botros *et al. 2007*, Choe *et al.* 2008]. Thus, resolution of urgency symptoms is associated with both traditional and modern mid-urethral sling surgery. The difference between traditional and modern incontinence surgery as regards urgency problems seems to be the occurrence of *de novo* urgency symptoms. Traditional incontinence operations have been associated with a risk of *de novo* urgency of 8-27% following Burch colposuspension and 3-23% following pubovaginal sling operation [Novara *et al.* 2010], whereas *de novo* urgency following mid-urethra slings have been 2%-9% [Ward and Hilton 2008, Ogah 2009].

In the present study 66% of the patients in both treatment groups were suffering from UUI preoperatively. Two months after operation 86% in the TVT group and 89% in the TVT-O group were cured of this symptom and after three years of follow-up the percentages were 75% and 73% in the TVT and TVT-O groups, respectively. There was no statistically significant difference between these procedures as regards resolution of UUI. Another study reported a resolution rate of UUI of 65% among patients in their TOT treatment group, compared with a rate of 48% in the TVT group after 3−9 months of follow-up, the difference not being statistically significant [Botros *et al.* 2007]. In the present study a DIS of more than seven was an exclusion criterion aimed at excluding women suffering from mixed incontinence. *De novo* urgency symptoms, defined as a DIS of >7, was recorded in 1.5%, 4.5% and 6.2% of the women after 2, 12 and 36 months, respectively, in the TVT group and in 3.1%, 3.1% and 5.6%, respectively, in the women in the TVT-O group. According to the review the TVT-O and the TOT procedures were found to be associated with higher rates of *de novo* urgency symptoms compared with that associated with the TVT procedure [Latthe *et al.* 2010]. In the retrospective analysis the women treated by means of the TOT procedure, on the other hand, had a significantly lower rate of *de novo* UUI (8%) than the women treated by means of the TVT operation (32%) after 9 months of follow-up [Botros *et al.* 2007]. The differences in reported rates of urgency symptoms between studies are very difficult to explain, because definitions and the questionnaires used are different. Randomized studies are currently regarded as being the most reliable methods to use in clinical studies when it comes to generating evidence of true differences between treatment alternatives.

Conclusions

In conclusion, the present study shows that the TVT operation is an effective and safe procedure even after eleven years follow-up, and there were no signs of late onset adverse effects. The TVT procedure can successfully be used as a repeat surgical procedure after immediate or later occurring failure of a primary mid-urethral operation. The TVT and TVT-O procedures show no statistically significant differences in efficacy and rate of complications after three years of follow-up. In most cases pre-existing urgency symptoms tend to resolve as a consequence of mid-urethral sling treatment and the risk of developing *de novo* urgency is low.

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REFERENCES

Abdel-Fattah M, Ford JA, Lim CP, Madhuvrata P. Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: A meta-analysis of effectiveness and complications. Eur Urol. 2011 Sep;60(3):468-80.

Abdel-Fattah M, Ramsay I, Pringle S, Hardwick C, Ali H, Young D, et al. Evaluation of transobturator tension-free vaginal tapes in management of women with recurrent stress urinary incontinence. Urology. 2011 May;77(5):1070-5.

Abrams P, Andersson KE, Birder L, Brubaker L, Cardozo L, Chapple C, et al. Fourth international consultation on incontinence recommendations of the international scientific committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse, and fecal incontinence. Neurourol Urodyn. 2010;29(1):213-40.

Abrams P, Blaivas JG, Stanton SL, Andersen JT. The standardisation of terminology of lower urinary tract function. The International Continence Society committee on standardisation of terminology. Scand J Urol Nephrol Suppl. 1988;114:5-19.

Agostini A, Bretelle F, Franchi F, Roger V, Cravello L, Blanc B. Immediate complications of tension-free vaginal tape (TVT): Results of a French survey. Eur J Obstet Gynecol Reprod Biol. 2006 Feb 1;124(2):237-9.

Ala-Nissila S, Haarala M, Makinen J. Tension-free vaginal tape - a suitable procedure for patients with recurrent stress urinary incontinence. Acta Obstet Gynecol Scand. 2010;89(2):210-6.

Albo ME, Richter HE, Brubaker L, Norton P, Kraus SR, Zimmern PE, et al. Burch colposuspension versus fascial sling to reduce urinary stress incontinence. N Engl J Med. 2007 May 24;356(21):2143-55.

Alcalay M, Monga A, Stanton SL. Burch colposuspension: A 10-20 year follow up. Br J Obstet Gynaecol. 1995 Sep;102(9):740-5.

Aldridge AH. Transplantation of fascia for relief of urinary incontinence. Am J Obstet Gynecol. 1942;44:398-411.

Alinsod R. Recent advances in tape slings for female urinary stress incontinence. Rev Obstet Gynecol. 2009 Winter;2(1):46-50.

Amaye-Obu FA, Drutz HP. Surgical management of recurrent stress urinary incontinence: A 12-year experience. Am J Obstet Gynecol. 1999 Dec;181(6):1296,307; discussion 1307-9.

Ashworth PD, Hagan MT. The meaning of incontinence: A qualitative study of non-geriatric urinary incontinence sufferers. J Adv Nurs. 1993 Sep;18(9):1415-23.

Asmussen M, Ulmsten U. A new technique for measurement of the urethra presure profile. Acta Obstet Gynecol Scand. 1976;55(2):167-73.

Asmussen M, Ulmsten U. On the physiology of continence and pathophysiology of stress incontinence in the female. Contrib Gynecol Obstet. 1983;10:32-50.

Awad SA, Flood HD, Acker KL. The significance of prior anti-incontinence surgery in women who present with urinary incontinence. J Urol. 1988 Sep;140(3):514-7.

Azam U, Frazer MI, Kozman EL, Ward K, Hilton P, Rane A. The tension-free vaginal tape procedure in women with previous failed stress incontinence surgery. J Urol. 2001 Aug;166(2):554-6.

Bergman A, Elia G. Three surgical procedures for genuine stress incontinence: Five-year follow-up of a prospective randomized study. Am J Obstet Gynecol. 1995 Jul;173(1):66-71.

Botros SM, Miller JJ, Goldberg RP, Gandhi S, Akl M, Beaumont JL, et al. Detrusor overactivity and urge urinary incontinence following trans obturator versus midurethral slings. Neurourol Urodyn. 2007;26(1):42-5.

Brooks R. EuroQol: The current state of play. Health Policy. 1996 Jul;37(1):53-72.

Burch JC. Cooper's ligament urethrovesical suspension for stress incontinence. nine years' experience–results, complications, technique. Am J Obstet Gynecol. 1968 Mar 15;100(6):764-74.

Chaikin DC, Rosenthal J, Blaivas JG. Pubovaginal fascial sling for all types of stress urinary incontinence: Long-term analysis. J Urol. 1998 Oct;160(4):1312-6.

Chapple CR, Wein AJ, Artibani W, Brubaker L, Haab F, Heesakkers JP, et al. A critical review of diagnostic criteria for evaluating patients with symptomatic stress urinary incontinence. BJU Int. 2005 Feb;95(3):327-34.

Choe JH, Choo MS, Lee KS. The impact of tension-free vaginal tape on overactive bladder symptoms in women with stress urinary incontinence: Significance of detrusor overactivity. J Urol. 2008 Jan;179(1):214-9.

Christensen H, Laybourn C, Eickhoff JH, Frimodt-Moller C. Long-term results of the stamey bladder-neck suspension procedure and of the Burch colposuspension. Scand J Urol Nephrol. 1997 Aug;31(4):349-53.

Clemens JQ, Stern JA, Bushman WA, Schaeffer AJ. Long-term results of the stamey bladder neck suspension: Direct comparison with the Marshall-Marchetti-Krantz procedure. J Urol. 1998 Aug;160(2):372-6.

Constantinou CE, Govan DE. Spatial distribution and timing of transmitted and reflexly generated urethral pressures in healthy women. J Urol. 1982 May;127(5):964-9.

Cornu JN, Sebe P, Peyrat L, Ciofu C, Cussenot O, Haab F. Midterm prospective evaluation of TVT-secur reveals high failure rate. Eur Urol. 2010 Jul;58(1):157-61.

Cross CA, Cespedes RD, McGuire EJ. Our experience with pubovaginal slings in patients with stress urinary incontinence. J Urol. 1998 Apr;159(4):1195-8.

Czaplicki M, Dobronski P, Torz C, Borkowski A. Long-term subjective results of Marshall-Marchetti-Krantz procedure. Eur Urol. 1998 Aug;34(2):118-23.

de Leval J. Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator vaginal tape inside-out. Eur Urol. 2003 Dec;44(6):724-30.

de Tayrac R, Salet-Lizee D, Villet R. Comparison of anterior colporrhaphy versus Bologna procedure in women with genuine stress incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 2002;13(1):36-9.

Debodinance P, Delporte P, Engrand JB, Boulogne M. Tension-free vaginal tape (TVT) in the treatment of urinary stress incontinence: 3 years experience involving 256 operations. Eur J Obstet Gynecol Reprod Biol. 2002 Oct 10;105(1):49-58.

Dekkers OM, von Elm E, Algra A, Romijn JA, Vandenbroucke JP. How to assess the external validity of therapeutic trials: A conceptual approach. Int J Epidemiol. 2010 Feb;39(1):89-94.

DeLancey JO. Structural support of the urethra as it relates to stress urinary incontinence: The hammock hypothesis. Am J Obstet Gynecol. 1994 Jun;170(6):1713,20; discussion 1720-3.

Delorme E. Transobturator urethral suspension: Mini-invasive procedure in the treatment of stress urinary incontinence in women. Prog Urol. 2001 Dec;11(6):1306-13.

Delorme E, Droupy S, de Tayrac R, Delmas V. Transobturator tape (uratape): A new minimally-invasive procedure to treat female urinary incontinence. Eur Urol. 2004 Feb;45(2):203-7.

Demirci F, Yildirim U, Demirci E, Ayas S, Arioglu P, Kuyumcuoglu U. Ten-year results of marshall marchetti krantz and anterior colporraphy procedures. Aust N Z J Obstet Gynaecol. 2002 Nov;42(5):513-4.

Deval B, Levardon M, Samain E, Rafii A, Cortesse A, Amarenco G, et al. A French multicenter clinical trial of SPARC for stress urinary incontinence. Eur Urol. 2003 Aug;44(2):254,8; discussion 258-9.

Dietz HP, Wilson PD. Colposuspension success and failure: A long-term objective follow-up study. Int Urogynecol J Pelvic Floor Dysfunct. 2000 Dec;11(6):346-51.

Dmochowski R, Scarpero H. Surgical outcomes reporting--closer to reality. Eur Urol. 2007 Nov;52(5):1306-8.

Drouin J, Tessier J, Bertrand PE, Schick E. Burch colposuspension: Long-term results and review of published reports. Urology. 1999 Nov;54(5):808-14.

Dwyer PL. The 75% rule: All stress incontinence procedures are alike. Int Urogynecol J Pelvic Floor Dysfunct. 2011 Jul;22(7):769-70.

Ek A. Adrenergic innervation and adrenergic mechanisms. A study of the human urethra. Acta Pharmacol Toxicol (Copenhagen) 1978;43 Suppl 2:35-40.

Emmet JL, Daut RV, Dunn JH. Role of the external urethral sphincter in the normal bladder and cord bladder. J Urol. 1948;59(3):439-54.

Enhorning G. Simultaneous recording of intravesical and intra-urethral pressure. A study on urethral closure in normal and stress incontinent women. Acta Chir Scand Suppl. 1961;Suppl 276:1-68.

Eriksen BC, Hagen B, Eik-Nes SH, Molne K, Mjolnerod OK, Romslo I. Long-term effectiveness of the Burch colposuspension in female urinary stress incontinence. Acta Obstet Gynecol Scand. 1990;69(1):45-50.

Falconer C, Ekman G, Malmstrom A, Ulmsten U. Decreased collagen synthesis in stress-incontinent women. Obstet Gynecol. 1994 Oct;84(4):583-6.

Farage MA, Miller KW, Berardesca E, Maibach HI. Psychosocial and societal burden of incontinence in the aged population: A review. Arch Gynecol Obstet. 2008 Apr;277(4):285-90.

Feyereisl J, Dreher E, Haenggi W, Zikmund J, Schneider H. Long-term results after Burch colposuspension. Am J Obstet Gynecol. 1994 Sep;171(3):647-52.

Frangenheim P. Zur operative behandlung der inkontinenz der männlichen harnröhre. Verh Dtsch Ges Chir. 1914;43:149-54.

Fulford SC, Flynn R, Barrington J, Appanna T, Stephenson TP. An assessment of the surgical outcome and urodynamic effects of the pubovaginal sling for stress incontinence and the associated urge syndrome. J Urol. 1999 Jul;162(1):135-7.

Galloway NT, Davies N, Stephenson TP. The complications of colposuspension. Br J Urol. 1987 Aug;60(2):122-4.

Gamble TL, Botros SM, Beaumont JL, Goldberg RP, Miller JJ, Adeyanju O, et al. Predictors of persistent detrusor overactivity after transvaginal sling procedures. Am J Obstet Gynecol. 2008 Dec;199(6):696.e1-7.

Ghoniem G, Stanford E, Kenton K, Achtari C, Goldberg R, Mascarenhas T, et al. Evaluation and outcome measures in the treatment of female urinary stress incontinence: International Urogynecological association (IUGA) guidelines for research and clinical practice. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Jan;19(1):5-33.

Giordano D. Twentieth Congress Franc de Chir. 1907;506-11.

Glazener CM, Cooper K. Anterior vaginal repair for urinary incontinence in women. Cochrane Database Syst Rev. 2001;(1)(1):CD001755.

Goebell R. Zur operative beseitigung der angebornen incontinentia vesicae. Zeitscrift Für Gynäkologische Urologie. 1910;2:187-91.

Groutz A, Blaivas JG, Rosenthal JE. A simplified urinary incontinence score for the evaluation of treatment outcomes. Neurourol Urodyn. 2000;19(2):127-35.

Hannestad YS, Rortveit G, Sandvik H, Hunskaar S. A community-based epidemiological survey of female urinary incontinence: The Norwegian EPINCONT study. J Clin Epidemiol. 2000 Nov;53(11):1150-7.

Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Int Urogynecol J Pelvic Floor Dysfunct. 2010 Jan;21(1):5-26.

Hellberg D, Holmgren C, Lanner L, Nilsson S. The very obese woman and the very old woman: Tension-free vaginal tape for the treatment of stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 2007 Apr;18(4):423-9.

Herbertsson G, Iosif CS. Surgical results and urodynamic studies 10 years after retropubic colpourethrocystopexy. Acta Obstet Gynecol Scand. 1993 May;72(4):298-301.

Herzog AR, Fultz NH. Prevalence and incidence of urinary incontinence in community-dwelling populations. J Am Geriatr Soc. 1990 Mar;38(3):273-81.

Hunskaar S, Lose G, Sykes D, Voss S. The prevalence of urinary incontinence in women in four european countries. BJU Int. 2004 Feb;93(3):324-30.

Imamura M, Abrams P, Bain C, Buckley B, Cardozo L, Cody J, et al. Systematic review and economic modelling of the effectiveness and cost-effectiveness of non-surgical treatments for women with stress urinary incontinence. Health Technol Assess. 2010 Aug;14(40):1-506.

Ingelman-Sundberg A. Urinary incontinence in women, excluding fistulas. Acta Obstet Gynecol Scand. 1952;31(3):266-91.

Irwin DE, Milsom I, Chancellor MB, Kopp Z, Guan Z. Dynamic progression of overactive bladder and urinary incontinence symptoms: A systematic review. Eur Urol. 2010 Jun 15.

Irwin DE, Milsom I, Hunskaar S, Reilly K, Kopp Z, Herschorn S, et al. Population-based survey of urinary incontinence, overactive bladder, and other lower urinary tract symptoms in five countries: Results of the EPIC study. Eur Urol. 2006 Dec;50(6):1306,14; discussion 1314-5.

Jarvis GJ. Surgery for genuine stress incontinence. Br J Obstet Gynaecol. 1994 May;101(5):371-4.

Karantanis E, Allen W, Stevermuer TL, Simons AM, O'Sullivan R, Moore KH. The repeatability of the 24-hour pad test. Int Urogynecol J Pelvic Floor Dysfunct. 2005 Jan-Feb;16(1):63,8; discussion 68.

Kauppila A, Alavaikko P, Kujansuu E. Detrusor instability score in the evaluation of stress urinary incontinence. Acta Obstet Gynecol Scand. 1982;61(2):137-41.

Kelleher CJ, Cardozo LD, Khullar V, Salvatore S. A new questionnaire to assess the quality of life of urinary incontinent women. Br J Obstet Gynaecol. 1997 Dec;104(12):1374-9.

Kelly HA, Dumm WM. Urinary incontinence in women, without manifest injury to the bladder. J Am Coll Surg. 1914;18:444-50.

Kennedy WT. Incontinence of urine in the female, the urethral sphincter mechanism, damage of function, and restoration of control. Am J Obstet Gynecol. 1937;34:576-87.

Kennelly MJ, Moore R, Nguyen JN, Lukban JC, Siegel S. Prospective evaluation of a single incision sling for stress urinary incontinence. J Urol. 2010 Aug;184(2):604-9.

Kenton K, Richter H, Litman H, Lukacz E, Leng W, Lemack G, et al. Risk factors associated with urge incontinence after continence surgery. J Urol. 2009 Dec;182(6):2805-9.

Kjolhede P. Long-term efficacy of burch colposuspension: A 14-year follow-up study. Acta Obstet Gynecol Scand. 2005 Aug;84(8):767-72.

Klovning A, Hunskaar S, Eriksen BC. Validity of a scored urological history in detecting detrusor instability in female urinary incontinence. Acta Obstet Gynecol Scand. 1996 Nov;75(10):941-5.

Kromann-Andersen B, Jakobsen H, Andersen JT. Pad-weighing test: a literature survey on test accuracy and reproducibility. Neurourol Urodyn. 1989;8:237-42.

Kulseng-Hanssen S, Berild GH. Subjective and objective incontinence 5 to 10 years after Burch colposuspension. Neurourol Urodyn. 2002;21(2):100-5.

Kulseng-Hanssen S, Husby H, Schiotz HA. Follow-up of TVT operations in 1,113 women with mixed urinary incontinence at 7 and 38 months. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Mar;19(3):391-6.

Kuuva N, Nilsson CG. Tension-free vaginal tape procedure: An effective minimally invasive operation for the treatment of recurrent stress urinary incontinence? Gynecol Obstet Invest. 2003;56(2):93-8.

Kuuva N, Nilsson CG. A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. Acta Obstet Gynecol Scand. 2002 Jan;81(1):72-7.

Labrie J, van der Graaf Y, Buskens E, Tiersma SE, van der Vaart HC. Protocol for physiotherapy or TVT randomised efficacy trial (PORTRET): A multicentre randomised controlled trial to assess the cost-effectiveness of the tension free vaginal tape versus pelvic floor muscle training in women with symptomatic moderate to severe stress urinary incontinence. BMC Womens Health. 2009 Sep 1;9:24.

Langer R, Lipshitz Y, Halperin R, Pansky M, Bukovsky I, Sherman D. Long-term (10-15 years) follow-up after Burch colposuspension for urinary stress incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 2001;12(5):323,6; discussion 326-7.

Lapitan MC, Cody JD, Grant A. Open retropubic colposuspension for urinary incontinence in women. Cochrane Database Syst Rev. 2009 Oct 7;(4)(4):CD002912.

Latthe PM, Foon R, Toozs-Hobson P. Transobturator and retropubic tape procedures in stress urinary incontinence: A systematic review and meta-analysis of effectiveness and complications. BJOG. 2007 May;114(5):522-31.

Latthe PM, Singh P, Foon R, Toozs-Hobson P. Two routes of transobturator tape procedures in stress urinary incontinence: A meta-analysis with direct and indirect comparison of randomized trials. BJU Int. 2010 Jul;106(1):68-76.

Laurikainen E, Kiilholma P. The tension-free vaginal tape procedure for female urinary incontinence without preoperative urodynamic evaluation. J Am Coll Surg. 2003 Apr;196(4):579-83.

Liapis A, Bakas P, Lazaris D, Creatsas G. Tension-free vaginal tape in the management of recurrent stress incontinence. Arch Gynecol Obstet. 2004 Mar;269(3):205-7.

Lim J, Cornish A, Carey MP. Clinical and quality-of-life outcomes in women treated by the TVT-O procedure. BJOG. 2006 Nov;113(11):1315-20.

Lim YN, Dwyer PL. Effectiveness of midurethral slings in intrinsic sphincteric-related stress urinary incontinence. Curr Opin Obstet Gynecol. 2009 Oct;21(5):428-33.

Lo TS, Horng SG, Chang CL, Huang HJ, Tseng LH, Liang CC. Tension-free vaginal tape procedure after previous failure in incontinence surgery. Urology. 2002 Jul;60(1):57- 61.

Lord HE, Taylor JD, Finn JC, Tsokos N, Jeffery JT, Atherton MJ, et al. A randomized controlled equivalence trial of short-term complications and efficacy of tension-free vaginal tape and suprapubic urethral support sling for treating stress incontinence. BJU Int. 2006 Aug;98(2):367-76.

Lose G, Fantl JA, Victor A, Walter S, Wells TL, Wyman J, et al. Outcome measures for research in adult women with symptoms of lower urinary tract dysfunction. standardization committee of the international continence society. Acta Obstet Gynecol Scand. 2001 Nov;80(11):981-5.

Lose G, Rosenkilde P, Gammelgaard J, Schroeder T. Pad-weighing test performed with standardized bladder volume. Urology. 1988 Jul;32(1):78-80.

Mainprize TC, Drutz HP. The Marshall-Marchetti-Krantz procedure: A critical review. Obstet Gynecol Surv. 1988 Dec;43(12):724-9.

Makinen J, Gronroos M, Kiilholma P, Tenho T, Pirhonen J, Erkkola R. Incidence of urinary incontinence in adult Finnish women. Duodecim. 1992;108(5):481-5.

Marchetti AA, Marshall VF, Shultis LD. Simple vesicourethral suspension; a survey. Am J Obstet Gynecol. 1957 Jul;74(1):57-63.

Marshall VF, Marchetti AA, Krantz KE. The correction of stress incontinence by simple vesicourethral suspension. Surg Gynecol Obstet. 1949 Apr;88(4):509-18.

Mcguire EJ, Lytton B. Pubovaginal sling procedure for stress incontinence. J Urol. 1978 Jan;119(1):82-4.

Meschia M, Barbacini P, Baccichet R, Buonaguidi A, Maffiolini M, Ricci L, et al. Short-term outcomes with the ajust system: A new single incision sling for the treatment of stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 2011 Feb;22(2):177-82.

Meschia M, Pifarotti P, Gattei U, Bertozzi R. Tension-free vaginal tape: Analysis of risk factors for failures. Int Urogynecol J Pelvic Floor Dysfunct. 2007 Apr;18(4):419-22.

Milsom I. The prevalence of urinary incontinence. Acta Obstet Gynecol Scand. 2000 Dec;79(12):1056-9.

Molden SM, Lucente VR. New minimally invasive slings: TVT secur. Curr Urol Rep. 2008 Sep;9(5):358-61.

Moore RD, Mitchell GK, Miklos JR. Single-center retrospective study of the technique, safety, and 12-month efficacy of the MiniArc single-incision sling: A new minimally invasive procedure for treatment of female SUI. Surg Technol Int. 2009;18:175-81.

Mourtzinos A. Are multichannel urodynamics required prior to surgery in a woman with stress urinary incontinence? Curr Urol Rep. 2010 Sep;11(5):323-7.

Neuman M. Perioperative complications and early follow-up with 100 TVT-SECUR procedures. J Minim Invasive Gynecol. 2008 Jul-Aug;15(4):480-4.

Nilsson CG, Falconer C, Rezapour M. Seven-year follow-up of the tension-free vaginal tape procedure for treatment of urinary incontinence. Obstet Gynecol. 2004 Dec;104(6):1259-62.

Nilsson CG, Kuuva N. The tension-free vaginal tape procedure is successful in the majority of women with indications for surgical treatment of urinary stress incontinence. BJOG. 2001 Apr;108(4):414-9.

Nilsson CG, Kuuva N, Falconer C, Rezapour M, Ulmsten U. Long-term results of the tension-free vaginal tape (TVT) procedure for surgical treatment of female stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 2001;12 Suppl 2:S5-8.

Novara G, Artibani W, Barber MD, Chapple CR, Costantini E, Ficarra V, et al. Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol. 2010 Aug;58(2):218-38.

Novara G, Galfano A, Boscolo-Berto R, Secco S, Cavalleri S, Ficarra V, et al. Complication rates of tension-free midurethral slings in the treatment of female stress urinary incontinence: A systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices. Eur Urol. 2008 Feb;53(2):288-308.

Nuotio M, Jylha M, Luukkaala T, Tammela TL. Urinary incontinence in a Finnish population aged 70 and over. Prevalence of types, associated factors and self-reported treatments. Scand J Prim Health Care. 2003 Sep;21(3):182-7.

Nygaard I. Urogynecology: The importance of long-term follow-up. Obstet Gynecol. 2006 Aug;108(2):244-5.

Ogah J, Cody JD, Rogerson L. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev. 2009 Oct 7;(4)(4):CD006375.

Okamura K, Nojiri Y, Osuga Y. Reliability and validity of the king's health questionnaire for lower urinary tract symptoms in both genders. BJU Int. 2009 Jun;103(12):1673-8.

Olsson I, Abrahamsson AK, Kroon UB. Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence: A retrospective follow-up 11.5 years post-operatively. Int Urogynecol J Pelvic Floor Dysfunct. 2010 Jun;21(6):679-83.

Palma P, Riccetto C, Reges R, Fraga R, Miyaoka R, Hermann V, et al. Arcus to arcus microsling: Technique and preliminary results. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Aug;19(8):1133-6.

Pereyra AJ. A simplified surgical procedure for the correction of stress incontinence in women. West J Surg Obstet Gynecol. 1959 Jul-Aug;67(4):223-6.

Petros PE, Ulmsten UI. An integral theory of female urinary incontinence. experimental and clinical considerations. Acta Obstet Gynecol Scand Suppl. 1990;153:7-31.

Petros PE, Woodman PJ. The integral theory of continence. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Jan;19(1):35-40.

Petrou SP, Frank I. Complications and initial continence rates after a repeat pubovaginal sling procedure for recurrent stress urinary incontinence. J Urol. 2001 Jun;165(6 Pt 1):1979-81.

Pinkhasov RM, Shteynshlyuger A, Hakimian P, Lindsay GK, Samadi DB, Shabsigh R. Are men short changed on health? Perspective on life expectancy, morbidity, and mortality in men and women in the United States. Int J Clin Pract. 2010 Mar;64(4):465-74.

Prien-Larsen JC, Hemmingsen L. Long-term outcomes of TVT and IVS operations for treatment of female stress urinary incontinence: monofilament vs. multifilament polypropylene tape. Int Urogynecol J Pelvic Floor Dysfunct. 2009 Jun;20(6):703-9.

Rabin R, de Charro F. EQ-5D: A measure of health status from the EuroQol group. Ann Med. 2001 Jul;33(5):337-43.

Raz S. Modified bladder neck suspension for female stress incontinence. Urology. 1981 Jan;17(1):82-5.

Rezapour M, Falconer C, Ulmsten U. Tension-free vaginal tape (TVT) in stress incontinent women with intrinsic sphincter deficiency (ISD) a long-term follow-up. Int Urogynecol J Pelvic Floor Dysfunct. 2001;12 Suppl 2:S12-14.

Rezapour M, Ulmsten U. Tension-free vaginal tape (TVT) in women with recurrent stress urinary incontinence − a long-term follow up. Int Urogynecol J Pelvic Floor Dysfunct. 2001;12 Suppl 2:S9-11.

Rezapour M, Ulmsten U. Tension-free vaginal tape (TVT) in women with mixed urinary incontinence a long-term follow-up. Int Urogynecol J Pelvic Floor Dysfunct. 2001;12 Suppl 2:S15-18.

Richter HE, Diokno A, Kenton K, Norton P, Albo M, Kraus S, et al. Predictors of treatment failure 24 months after surgery for stress urinary incontinence. J Urol. 2008 Mar;179(3):1024-30.

Roth CC, Winters JC, Woodruff AJ. What's new in slings: An update on midurethral slings. Curr Opin Urol. 2007 Jul;17(4):242-7.

Rothwell PM. Commentary: External validity of results of randomized trials: Disentangling a complex concept. Int J Epidemiol. 2010 Feb;39(1):94-6.

Ryhammer AM, Djurhuus JC, Laurberg S. Pad testing in incontinent women: A review. Int Urogynecol J Pelvic Floor Dysfunct. 1999;10(2):111-5.

Samuelsson EC, Victor FT, Svardsudd KF. Five-year incidence and remission rates of female urinary incontinence in a Swedish population less than 65 years old. Am J Obstet Gynecol. 2000 Sep;183(3):568-74.

Sand PK, Bowen LW, Panganiban R, Ostergard DR. The low pressure urethra as a factor in failed retropubic urethropexy. Obstet Gynecol. 1987 Mar;69(3 Pt 1):399-402.

Sarver R, Govier FE. Pubovaginal slings: Past, present and future. Int Urogynecol J Pelvic Floor Dysfunct. 1997;8(6):358-68.

Schrepferman CG, Griebling TL, Nygaard IE, Kreder KJ. Resolution of urge symptoms following sling cystourethropexy. J Urol. 2000 Nov;164(5):1628-31.

Segal JL, Vassallo B, Kleeman S, Silva WA, Karram MM. Prevalence of persistent and *de novo* overactive bladder symptoms after the tension-free vaginal tape. Obstet Gynecol. 2004 Dec;104(6):1263-9.

Shumaker SA, Wyman JF, Uebersax JS, McClish D, Fantl JA. Health-related quality of life measures for women with urinary incontinence: The incontinence impact questionnaire and the urogenital distress inventory. continence program in women (CPW) research group. Qual Life Res. 1994 Oct;3(5):291-306.

Siegel AL, Kim M, Goldstein M, Levey S, Ilbeigi P. High incidence of vaginal mesh extrusion using the intravaginal slingplasty sling. J Urol. 2005 Oct;174(4 Pt 1):1308-11.

Siltberg H, Victor A, Larsson G. Pad weighing tests: The best way to quantify urine loss in patients with incontinence. Acta Obstet Gynecol Scand Suppl. 1997;166:28-32.

Small WP. Lost to follow-up. Lancet. 1967 May 6;1(7497):997-9.

Stach-Lempinen B, Kujansuu E, Laippala P, Metsanoja R. Visual analogue scale, urinary incontinence severity score and 15 D – psychometric testing of three different health-related quality-of-life instruments for urinary incontinent women. Scand J Urol Nephrol. 2001 Dec;35(6):476-83.

Stamey TA. Endoscopic suspension of the vesical neck for urinary incontinence in females. Report on 203 consecutive patients. Ann Surg. 1980;192(4):465-71.

Stamey TA, Schaeffer AJ, Condy M. Clinical and roentgenographic evaluation of endoscopic suspension of the vesical neck for urinary incontinence. Surg Gynecol Obstet. 1975 Mar;140(3):355-60.

Stoeckel W. Über die verwendung der musculi pyramidalis bei der operativen behandlung der incontinentia urinae. Zentralbl f Gynäk. 1917;41:11-19.

Subak LL, Brubaker L, Chai TC, Creasman JM, Diokno AC, Goode PS, et al. High costs of urinary incontinence among women electing surgery to treat stress incontinence. Obstet Gynecol. 2008 Apr;111(4):899-907.

Sutherst J, Brown M, Shawer M. Assessing the severity of urinary incontinence in women by weighing perineal pads. Lancet. 1981 May 23;1(8230):1128-30.

Swift SE, Ostergard DR. Evaluation of current urodynamic testing methods in the diagnosis of genuine stress incontinence. Obstet Gynecol. 1995 Jul;86(1):85-91.

Swift SE, Yoon EA. Test-retest reliability of the cough stress test in the evaluation of urinary incontinence. Obstet Gynecol. 1999 Jul;94(1):99-102.

Tamussino K, Hanzal E, Kolle D, Ralph G, Riss P, Austrian Urogynecology Working Group. The Austrian tension-free vaginal tape registry. Int Urogynecol J Pelvic Floor Dysfunct. 2001;12 Suppl 2:S28-9.

Thom DH, Brown JS, Schembri M, Ragins AI, Subak LL, Van Den Eeden SK. Incidence of and risk factors for change in urinary incontinence status in a prospective cohort of middle-aged and older women: The reproductive risk of incontinence study in Kaiser. J Urol. 2010 Oct;184(4):1394-401.

Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA. Short forms to assess life quality and symptom distress for urinary incontinence in women: The incontinence impact questionnaire and the urogenital distress inventory. continence program for women research group. Neurourol Urodyn. 1995;14(2):131-9.

Ulmsten U. Simultaneous urethro-cystometry in the diagnosis of female urinary incontinence. Ann Chir Gynaecol. 1982;71(4):189-96.

Ulmsten U, Asmussen M, Lindstrom K. A new technique for simultaneous urethrocystometry including measurements of the urethral pressure profile. Urol Int. 1977;32(2-3):127-36.

Ulmsten U, Ekman G, Giertz G, Malmstrom A. Different biochemical composition of connective tissue in continent and stress incontinent women. Acta Obstet Gynecol Scand. 1987;66(5):455-7.

Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 1996;7(2):81,5; discussion 85-6.

Ulmsten U, Petros P. Intravaginal slingplasty (IVS): An ambulatory surgical procedure for treatment of female urinary incontinence. Scand J Urol Nephrol. 1995 Mar;29(1):75-82.

Ulmsten U, Sjoberg NO, Alm P, Andersson KE, Owman C, Walles B. Functional role of an adrenergic sphincter in the female urethra of the guinea-pig. Acta Obstet Gynecol Scand. 1977;56(4):387-90.

van Geelen JM, Theeuwes AG, Eskes TK, Martin CB,Jr. The clinical and urodynamic effects of anterior vaginal repair and Burch colposuspension. Am J Obstet Gynecol. 1988 Jul;159(1):137-44.

Versi E, Orrego G, Hardy E, Seddon G, Smith P, Anand D. Evaluation of the home pad test in the investigation of female urinary incontinence. Br J Obstet Gynaecol. 1996 Feb;103(2):162-7.

Ward KL, Hilton P, UK and Ireland TVT Trial Group. Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. BJOG. 2008 Jan;115(2):226-33.

Ware JE,Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual frame work and item selection. Med Care. 1992 Jun;30(6):473-83.

Weber AM, Taylor RJ, Wei JT, Lemack G, Piedmonte MR, Walters MD. The cost-effectiveness of preoperative testing (basic office assessment vs. urodynamics) for stress urinary incontinence in women. BJU Int. 2002 Mar;89(4):356-63.

Wennberg AL, Molander U, Fall M, Edlund C, Peeker R, Milsom I. A longitudinal population-based survey of urinary incontinence, overactive bladder, and other lower urinary tract symptoms in women. Eur Urol. 2009 Apr;55(4):783-91.

Westby M, Asmussen M, Ulmsten U. Location of maximum intraurethral pressure related to urogenital diaphragm in the female subject as studied by simultaneous urethrocystometry and voiding urethrocystography. Am J Obstet Gynecol. 1982 Oct 15;144(4):408-12.

Yamada BS, Govier FE, Stefanovic KB, Kobashi KC. High rate of vaginal erosions associated with the mentor ObTape. J Urol. 2006 Aug;176(2):651,4; discussion 654.

Zacharin RF. The anatomic supports of the female urethra. Obstet Gynecol. 1968 Dec;32(6):754-9.

Virtsan karkaamisen haitta-aste

Nimi		Pvm	
Henkilötunnus	Ongelma esiintynyt		kk/vuotta
Haitta-aste %	Pituus	Paino	Ikä

Merkitkää rastilla sopivin vaihtoehto		**Ei 0 p.**	**Joskus 1 p.**	**Usein 2 p.**
1.	Karkaako Teiltä virtsa ilman ponnistusta ja asennosta riippumatta (esim. makuulla)?			
2.	Esiintyykö virtsan karkaaminen (vasta) vähäisessä ponnistuksessa (esim. seisomaan noustessa, kävellessä)?			
3.	Karkaako Teiltä virtsaa (vasta) yhtäkkisissä, voimakkaissa ponnistuksissa (esim. aivastaessa, yskiessä, juostessa)?			
4.	Haittaavatko karkailuoireet päivittäisiä askareitanne (kaupassakäynti, ruuanlaitto, siivous tms.)?			
5.	Onko oireistanne haittaa ansiotyössänne (asiakkaiden palveleminen, työsuoritukset tms.)?			
6.	Pelkäättekö, että muut huomaavat vaivanne (haju, märkyys tms.)?			
7.	Joudutteko luopumaan menoistanne (liikunta, kyläily, teatteri, kirkko tms.)?			
8.	Haittaavatko karkailuoireet sukupuolielämäänne?			
9.	Aiheuttaako karkailu ulkosynnyttimienne ärtymistä?			
10.	Joudutteko käyttämään suojavaippoja tai -siteitä?			

Virtsan karkaamisen erotuspisteet

Nimi		Pvm	
Henkilötunnus	Ongelma esiintynyt		kk/vuotta
Pisteet yhteensä	Pituus	Paino	Ikä

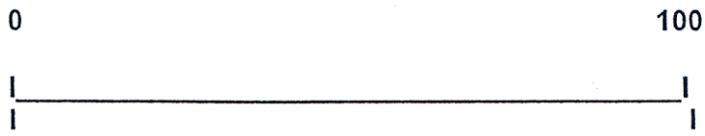
Merkitkää rastilla sopivin vaihtoehto	**0 p.**	**1 p.**	**2 p.**
1. Montako kertaa käytte virtsalla päivisin?	☐ 5–7	☐ 8–10	☐ yli 10
2. Montako kertaa joudutte öisin nousemaan virtsalle?	☐ 0–1	☐ 2–3	☐ yli 3
3. Tuntuuko Teistä, että virtsarakkoon jää virtsaa WC-käynnin jälkeen?	☐ Ei	☐ Joskus	☐ Usein
4. Aiheuttaako kiire tai jännitys Teille virtsaamispakkoa?	☐ Ei	☐ Joskus	☐ Usein
5. Karkaako Teiltä virtsaa ponnistamistilanteissa muulloinkin (esim. yskäisy, aivastus, nauru)?	☐ Kyllä	☐ Joskus	☐ Ajoittain muulloinkin
6. Karkaako virtsa välittömästi em. ponnistuksen yhteydessä?	☐ Kyllä	☐ En osaa sanoa	☐ Jälkeen
7. Tunnetteko virtsaamistarvetta ennen virtsan karkaamista?	☐ Ei	☐ Joskus	☐ Usein
8. Paljonko Teiltä karkaa virtsaa kerrallaan?	☐ Tippa	☐ Liraus	☐ Enemmän
9. Pystyttekö virtsatessanne keskeyttämään virtsasuihkun?	☐ Kyllä	☐ Aika hyvin	☐ En
10. Onko Teillä ollut hoidettuja virtsatietulehduksia viimeisten kahden vuoden aikana?	☐ Ei	☐ 1–2	☐ yli2/ kroonisesti

VAS (Visuaali analogi skaala)

VIRTSAAMISOIREIDEN VAIKEUSASTE

Kuinka häiritsevä on virtsavaivanne ? (merkitkää rasti alla olevalle janalle)

0 = ei lainkaan häiritsevä **100 = pahin kuviteltavissa oleva häiriö**



IIQ-7

Incontinence Impact Questionnaire – short form

Olkaa hyvä ja rastittakaa oireisiinne parhaiten sopiva ruutu :

Onko virtsankarkailu vaikuttanut:	ei lainkaan	hieman	kohtalaisesti	suuressa määrin
Kotiaskareisiinne				
Liikuntaharrastuksiinne				
Muihin harrastuksiinne				
Matkustamiseen (> 30 min matka kotoa)				
Sosiaaliseen kanssakäymiseen				
Tunne-elämäänne (mm. hermostuminen, masentuneisuus)				
Aiheuttanut turhautumisen tunnetta				

UDI-6

Urogenital Distress Inventory – short form

Olkaa hyvä ja rastittakaa oireisiinne parhaiten sopiva ruutu:

Esiintyykö Teillä seuraavia oireita ja miten hankalina?	ei lainkaan	hieman	kohtalaisesti	suuressa määrin
Tihentynyt virtsaamistarve				
Virtsankarkailua, johon liittyy pakottava virtsaamistarve				
Virtsankarkailua liittyen ponnistus-tilanteisiin, yskimiseen tai aivastamiseen				
Virtsaa karkaa tipottain, pieniä määriä				
Hankaluuksia tyhjentää rakkoa				
Kipuja alavatsalla tai ulkosynnyttimien alueella				

EQ – 5D
Terveyskysely
(Suomalainen versio)

Olkaa hyvä ja merkitkää rastilla (x), yksi rasti kunkin alla olevan ryhmän kohdalle, mikä seuraavista kolmesta väitteestä kuvaa parhaiten terveydentilaanne tänään:

Liikkuminen

( ) Minulla ei ole vaikeuksia kävelemisessä
( ) Minulla on jonkin verran vaikeuksia kävelemisessä
( ) Olen vuoteenomana

Itsestä huolehtiminen

( ) Minulla ei ole vaikeuksia huolehtia itsestäni
( ) Minulla on jonkin verran vaikeuksia peseytyä tai pukeutua itse
( ) En kykene peseytymään tai pukeutumaan itse

Tavanomaiset toiminnot

( ) Minulla ei ole vaikeuksia suorittaa tavanomaisia toimintojani (esim. ansiotyö, opiskelu, kotityö, vapaa-ajan toiminnot)
( ) Minulla on jonkin verran vaikeuksia suorittaa tavanomaisia toimintojani
( ) En kykene suorittamaan tavanomaisia toimintojani

Kipu tai vaiva

( ) Minulla ei ole kipuja eikä vaivoja
( ) Minulla on kohtalaisia kipuja tai vaivoja
( ) Minulla on ankaria kipuja tai vaivoja

Mieliala

( ) En ole ahdistunut enkä masentunut
( ) Olen melko ahdistunut tai masentunut
( ) Olen erittäin ahdistunut tai masentunut

Verrattuna keskimääräiset terveydentilaani viimeisten 12 kuukauden aikana, terveydentilani tällä hetkellä on

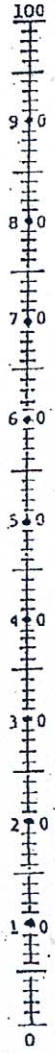
( ) Parempi
( ) Suunnilleen sama
( ) Huonompi

EQ – 5D
Terveyskysely
(Suomalainen versio)

Auttaaksemme Teitä arvioimaan kuinka hyvä tai huono jokin terveydentila on, olemme piirtäneet oheen lämpömittaria muistuttavan asteikon. Parasta terveydentilaa, jonka voitte kuvitella, merkitään siinä 100:lla ja huonointa 0:lla.

Pyydämme Teitä nyt merkitsemään oheiselle asteikolle, millainen on terveydentilanne tänään. Olkaa hyvä ja vetäkää alla olevasta laatikosta viiva siihen kohtaan asteikolle, joka parhaiten kuvaa tämänhetkistä terveydentilaanne.

Paras kuviteltavissa oleva terveydentila



Terveydentilani tänään

Huonoin kuviteltavissa oleva terveydentila